

Dated: March 31, 1997.

**G. Martin Wagner,**

Associate Administrator, Office of Governmentwide Policy.

**Attachment**

March 31, 1997.

[GSA Bulletin FTR 25]

To: Heads of Federal agencies.

Subject: Promoting, Encouraging, and Facilitating the Use of Firesafe Accommodations.

**1. Purpose**

This bulletin informs agencies that pursuant to the Federal Travel Regulation (FTR) (41 CFR 301-304) each agency is responsible for influencing its employees who require commercial lodging when performing official travel to stay at an approved firesafe accommodation. Further, Federal employees traveling on official business, and pre-employment interviewees, are strongly encouraged to stay at an approved accommodation as defined in FTR § 301-17.2(c).

**2. Background**

a. The Hotel and Motel Fire Safety Act of 1990, Pub. L. No. 101-391, 104 stat. 747 (codified as amended in scattered sections of 15 U.S.C. and 5 U.S.C.) (the Act) requires the development and issuance of guidelines, and sets standards, concerning the use and installation of automatic sprinkler systems and smoke detectors in places of public accommodation affecting commerce.

b. In September 1994, the General Services Administration (GSA) issued FTR Amendment 39 (59 FR 46192, Sept. 7, 1994) instructing agencies, among other things, to ensure that each agency achieve an adequate "approved accommodations percentage" as specified in the Act, and reflected in the FTR, to enhance the safety of Federal employees traveling on official business. An "approved accommodations percentage" is the percentage of nights that an agency's employees traveling on official business spend in approved accommodations, i.e., any place of public accommodation that meets the requirements of the fire prevention and control guidelines in 15 U.S.C. 2225, relative to the total number of nights spent in places of public accommodation.

c. Section 1614 of the National Defense Authorization Act for Fiscal Year 1997, Pub. L. No. 104-201, 110 Stat. 2739, repealed the "approved accommodations" data collection and employee reporting requirement imposed by the Act.

d. In December 1996, GSA issued FTR Amendment 53 (61 FR 64997, Dec. 10, 1996) to eliminate the "approved accommodations" data collection and reporting requirement.

e. GSA is issuing the guidelines contained in this bulletin to inform agencies that although the data collection and reporting requirement was repealed, the provisions that encourage agencies to promote the use of "approved accommodations" or require, with limited exception, the use of "approved accommodations" for conferences were not repealed. Agencies, therefore, should continue to effectuate policies strongly

encouraging employees to use "approved accommodations".

**3. Hotel and Motel Fire Safety Guidelines**

The Act sets standards for fire prevention and control in places of public accommodation affecting commerce. These requirements include installation of hard-wired, single station smoke detectors in each guest room of each place of public accommodation, and an automatic sprinkler system in each place of public accommodation that is more than three stories. The Act further requires each State to submit to the Director of the Federal Emergency Management Agency (FEMA) a list of places of public accommodation in the State that comply with the Act's fire safety standards. From the State lists, FEMA must compile and publish in the **Federal Register** a national master list and distribute it to each Federal agency. The Act requires FEMA to periodically update the master list based on information provided by the States, and to distribute the updated list to each agency. Any questions regarding the FEMA list may be directed to Mr. John Ottoson, United States Fire Administration, at (301) 447-1272. The list is available via the internet at <http://www.usfa.fema.gov/hotel/hotelindex>.

**4. Federal Travel Program Compliance**

It is the policy of the Federal Government to save lives and protect property by promoting fire safety in hotels, motels, and all places of public accommodation affecting commerce. The GSA's travel programs adhere to established fire safety guidelines and survey accommodations that meet fire safety standards when conducting surveys of lodging costs for the purpose of establishing locality per diem rates.

**5. Federal Agency Compliance**

a. Pursuant to FTR § 301-7.2(b)(2), it is the responsibility of each agency when authorizing travel to take appropriate measures to influence employees, and others who will procure commercial lodging in the performance of official travel, to stay at a firesafe approved accommodation.

b. Pursuant to FTR part 301-16, an agency may not sponsor or fund in whole or in part a conference at a place of public accommodation that is not an approved accommodation, unless a waiver is granted.

**6. Other Fire Safety Responsibilities**

a. Pursuant to FTR § 301-1.3(a)(2), employees are strongly encouraged to stay in an approved accommodation when commercial lodging is required.

b. Pursuant to FTR § 301-1.202(b)(6), an interviewee traveling to a pre-employment interview is strongly encouraged to stay at an approved accommodation when commercial lodging is required.

**7. Expiration Date**

This bulletin remains in effect until canceled or superseded.

**8. For Further Information Contact**

Jane E. Groat, General Services Administration, Office of Governmentwide Policy (MTT), Washington, DC 20405; e-mail,

[jane.groat@gsa.gov](mailto:jane.groat@gsa.gov); telephone (202) 501-1538.

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**Notice of Specific List for Categorization of Laboratory Test Systems, Assays, and Examinations by Complexity.**

**AGENCY:** Centers for Disease Control and Prevention (CDC), HHS.

**ACTION:** Notice with comment period.

**SUMMARY:** Regulations codified at 42 CFR 493.17, implementing the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 100-578, require that the Secretary provide for the categorization of specific laboratory test systems, assays, and examinations by level of complexity. The criteria for such categorizations also are set forth in those regulations.

This Notice announces the addition of approximately 1,300 test systems, assays, and examinations that have been categorized and notified between June 7, 1996 and December 31, 1996. These categorizations were effective on the issue date of the notification letter sent to the manufacturer and are subject to the 30 day comment period for this Notice.

**DATES: Effective date:** All categorizations in this Notice were effective on the date of the test categorization notification letter sent to the manufacturer. Written comments on the tests initially categorized in this Notice will be considered if they are received at the address indicated below, by no later than 5 p.m. on May 12, 1997. CDC reserves the right to reevaluate and recategorize tests based on the comments received in response to this Notice.

**ADDRESSES:** Comments on the categorization of tests in this Notice should be addressed to CLIA Federal Register Notice, Centers for Disease Control and Prevention, Mail Stop F-11, 4770 Buford Highway, NE, Atlanta, Georgia 30341-3724.

Requests for test complexity categorization should be submitted to: Attention: Test Categorization/CLIA, Centers for Disease Control and Prevention, Mail Stop F-11, 4770 Buford Highway, NE, Atlanta, Georgia 30341-3724.

Requests for waiver status should be submitted to: Attention: Request for Waiver Status/CLIA, Centers for Disease Control and Prevention, Mail Stop F-11, 4770 Buford Highway, NE, Atlanta, GA 30341-3724.

We will not be accepting facsimile (fax) copies or comments by telephone. **FOR FURTHER INFORMATION CONTACT:** Rosemary C. Bakes-Martin, (770) 488-7655.

**SUPPLEMENTARY INFORMATION:** All requests for test categorization should be submitted to the CDC. CDC is reviewing submissions for test categorization concurrently with the FDA's review process for 510(k) clearance or Pre-Market Approval (PMA) clearance. In order to assure timely review by CDC, manufacturers are requested to submit the package insert and 510(k) number for the product to CDC when the product is submitted to the FDA. However, CDC will not be able to issue the test categorization until the FDA has finished its review process. CDC is currently issuing test categorization notification letters to manufacturers within one week of the FDA 510(k) or PMA clearance. Test categorizations are effective as of the date of notification to the applicant. The CDC will publish updates and revisions to the test categorization list periodically in the **Federal Register** with opportunity for comment. The CDC will also maintain an updated list of categorized tests electronically, available to the public via Internet. For further information regarding this capability, please call (770) 488-7655.

#### Comments and Responses

On July 8, 1996, a test list of approximately 2,400 additional test systems, assays, and examinations categorized by level of complexity was published in the **Federal Register** (61 FR 35736) with a 30 day comment period. CDC received no comment letters in regard to this Notice.

#### Analyte Clarification

Confusion has arisen over the nomenclature and related specialty/subspecialty of the analytes (2512) *Helicobacter pylori* in the specialty/subspecialty of Bacteriology and (2513) *Helicobacter pylori* Antibodies in the specialty/subspecialty of General Immunology. The analyte (2512) *Helicobacter pylori* is used with those test systems that detect urease production by the *Helicobacter pylori* organism in a tissue specimen which is considered a bacteriology procedure. The analyte (2513) *Helicobacter pylori*

Antibodies is used for the detection of antibodies to *Helicobacter pylori* in serum which is considered an immunology procedure.

For better definition, and where appropriate, a new analyte, (0525) Anti-Proteinase (PR-3) Antibodies, has replaced the less specific analyte (0440) Anti-Neutrophil Cytoplasm Antibodies.

For accuracy, the analyte (4973) Protein C Resistance has been changed to (0526) Activated Protein C (APC) Resistance.

Dated: April 3, 1997.

#### Joseph R. Carter,

*Acting Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).*

#### List of Previously Unpublished Categorizations

The test categorization scoring scheme was based on an assessment of the complexity of the operation of the test procedure and not on an evaluation of data documenting the procedure's performance over time. Therefore, the categorization of a test system, assay, or examination as moderate or high complexity should not be interpreted as an indication of the acceptability or unacceptability of the accuracy, precision, or overall performance of the procedure.

COMPLEXITY: MODERATE  
SPECIALITY/SUBSPECIALITY:

Bacteriology  
ANALYTE: Aerobic &/or Anaerobic Organisms—unlimited sources (0412)

TEST SYSTEM ASSAY,  
EXAMINATION:

Becton Dickinson BACTEC 9050 (07809)  
ANALYTE: *Clostridium difficile* (1022)

TEST SYSTEM ASSAY,  
EXAMINATION:

Meridian Diagnostics ImmunoCard Toxin A (dir. sample/vis) (40255)  
Unipath Clearview C. DIFF A (64033)  
bioMerieux Vitek VIDAS (07806)  
ANALYTE: *Streptococcus*, group A (from throat only) (5828)

TEST SYSTEM ASSAY,  
EXAMINATION:

CliniCare CliniStrip NOW Strep A (10386)  
CliniCare CliniStrip Strep A (10385)  
SPECIALITY/SUBSPECIALITY:  
Endocrinology  
ANALYTE: Cortisol (1032)

TEST SYSTEM, ASSAY,  
EXAMINATION:

Chiron Diagnostics ACS 180 (10375)  
Chiron Diagnostics ACS 180 Plus

(10376)  
Ciba Corning ACS 180 Plus (10336)  
bioMerieux Vitek VIDAS (07806)  
ANALYTE: Cortisol, Urine (direct procedure) (1033)

TEST SYSTEM, ASSAY,  
EXAMINATION:

Chiron Diagnostics ACS 180 (10375)  
Chiron Diagnostics ACS 180 Plus (10376)  
Ciba Corning ACS 180 Plus (10336)  
ANALYTE: Estradiol (1605)

TEST SYSTEM, ASSAY,  
EXAMINATION:

Behring OPUS (07793)  
Behring OPUS Magnum (07794)  
Behring OPUS Plus (07795)  
Chiron Diagnostics ACS 180 (10375)  
Chiron Diagnostics ACS 180 Plus (10376)  
Ciba Corning ACS 180 Plus (10336)  
bioMerieux Vitek VIDAS (07806)  
ANALYTE: Follicle Stimulating Hormone (FSH) (1908)

TEST SYSTEM, ASSAY,  
EXAMINATION:

Behring OPUS (07793)  
Chiron Diagnostics ACS 180 (10375)  
Chiron Diagnostics ACS 180 Plus (10376)  
Ciba Corning ACS 180 Plus (10336)  
Dade aca Star with aca plus Immunoassay System (13424)  
bioMerieux Vitek VIDAS (07806)  
ANALYTE: HCG Beta Serum, Quantitative—Extended Range (ER) (2566)

TEST SYSTEM, ASSAY,  
EXAMINATION:

Technicon Immuno 1 System (61042)  
ANALYTE: HCG, Beta, Serum, Quantitative (2502)

TEST SYSTEM, ASSAY,  
EXAMINATION:

Behring OPUS (07793)  
Boehringer Mannheim Elecsys 2010 Analyzer (07810)  
Chiron Diagnostics ACS 180 (10375)  
Chiron Diagnostics ACS 180 Plus (10376)  
Ciba Corning ACS 180 Plus (10336)  
Dade aca Star with aca plus Immunoassay System (13424)  
bioMerieux Vitek VIDAS (07806)  
ANALYTE: HCG, Serum, Qualitative (2501)

TEST SYSTEM, ASSAY,  
EXAMINATION:

Biocircuits IOS (07745)  
Bionike A/Q Pregnancy Test (07779)  
CliniCare CliniStrip hCG Combo (10384)  
Genzyme Contrast Strip hCG (22185)

Orion Diagnostica UniStep hCG II (46224)  
ANALYTE: HCG, Total, Serum, Quantitative (2555)

*TEST SYSTEM, ASSAY, EXAMINATION:*

Behring OPUS (07793)  
Behring OPUS Magnum (07794)  
Behring OPUS Plus (07795)  
Biocircuits IOS (07745)  
Chiron Diagnostics ACS 180 (10375)  
Chiron Diagnostics ACS 180 Plus (10376)  
Ciba Corning ACS 180 Plus (10336)  
ANALYTE: HCG, Urine, Qualitative (non-waived procedures) (2503)

*TEST SYSTEM, ASSAY, EXAMINATION:*

TECO Diagnostics Monoclonal B-hCG Pregnancy Test (Indirect) (61255)  
ANALYTE: HCG, Urine, Quantitative (2534)

*TEST SYSTEM, ASSAY, EXAMINATION:*

Behring OPUS (07793)  
Behring OPUS Magnum (07794)  
Behring OPUS Plus (07795)  
ANALYTE: Luteinizing Hormone (LH) (3713)

*TEST SYSTEM, ASSAY, EXAMINATION:*

Behring OPUS (07793)  
Chiron Diagnostics ACS 180 (10375)  
Chiron Diagnostics ACS 180 Plus (10376)  
Ciba Corning ACS 180 Plus (10336)  
Dade aca Star with aca plus Immunoassay System (13424)  
bioMerieux Vitek VIDAS (07806)  
ANALYTE: Progesterone (4914)

*TEST SYSTEM, ASSAY, EXAMINATION:*

Chiron Diagnostics ACS 180 (10375)  
Chiron Diagnostics ACS 180 Plus (10376)  
Ciba Corning ACS 180 Plus (10336)  
ANALYTE: Prolactin (4915)

*TEST SYSTEM, ASSAY, EXAMINATION:*

Behring OPUS (07793)  
Chiron Diagnostics ACS 180 (10375)  
Chiron Diagnostics ACS 180 Plus (10376)  
Ciba Corning ACS 180 Plus (10336)  
Dade aca Star with aca plus Immunoassay System (13424)  
bioMerieux Vitek VIDAS (07806)  
ANALYTE: T Uptake (TU) (6156)

*TEST SYSTEM, ASSAY, EXAMINATION:*

Boehringer Mannheim Elecsys 2010 Analyzer (07810)

Chiron Diagnostics 550 Express (10352)  
Dade Dimension AR (13421)  
Dade Dimension ES (13420)  
Dade Dimension RxL (13436)  
Dade Dimension XL (13422)  
Dade aca Star (13423)  
bioMerieux Vitek VIDAS (07806)  
ANALYTE: Testosterone (6102)

*TEST SYSTEM, ASSAY, EXAMINATION:*

Chiron Diagnostics ACS 180 (10375)  
Chiron Diagnostics ACS 180 Plus (10376)  
Ciba Corning ACS 180 Plus (10336)  
Cirrux Diagnostics Immulite (10159)  
Technicon Immuno 1 System (61042)  
ANALYTE: Thyroid Stimulating Hormone (TSH) (6106)

*TEST SYSTEM, ASSAY, EXAMINATION:*

Behring OPUS (07793)  
Biocircuits IOS (07745)  
Boehringer Mannheim Elecsys 2010 Analyzer (07810)  
Chiron Diagnostics ACS 180 (10375)  
Chiron Diagnostics ACS 180 Plus (10376)  
Ciba Corning ACS 180 Plus (10336)  
CliniCare CliniStrip ThyroChek TSH (10387)

Dade aca Star with aca plus Immunoassay System (13424)  
bioMerieux Vitek VIDAS (07806)  
ANALYTE: Thyroxine (T4) (6109)

*TEST SYSTEM, ASSAY, EXAMINATION:*

Behring OPUS (07793)  
Boehringer Mannheim Elecsys 2010 Analyzer (07810)  
Chiron Diagnostics 550 Express (10352)  
Chiron Diagnostics ACS 180 (10375)  
Chiron Diagnostics ACS 180 Plus (10376)

Ciba Corning ACS 180 Plus (10336)  
Dade Dimension RxL (13436)  
Dade Dimension XL (13422)  
Dade aca Star (13423)  
bioMerieux Vitek VIDAS (07806)  
ANALYTE: Thyroxine, Free (FT4) (6111)

*TEST SYSTEM, ASSAY, EXAMINATION:*

Behring OPUS (07793)  
Behring OPUS Magnum (07794)  
Behring OPUS Plus (07795)  
Boehringer Mannheim Elecsys 2010 Analyzer (07810)  
Chiron Diagnostics ACS 180 (10375)  
Chiron Diagnostics ACS 180 Plus (10376)  
Ciba Corning ACS 180 Plus (10336)  
Du Pont ACA IV with aca plus Immunoassay System (13254)

bioMerieux Vitek VIDAS (07806)  
ANALYTE: Triiodothyronine (T3) (6119)

*TEST SYSTEM, ASSAY, EXAMINATION:*

Behring OPUS (07793)  
Boehringer Mannheim Elecsys 2010 Analyzer (07810)  
Chiron Diagnostics ACS 180 (10375)  
Chiron Diagnostics ACS 180 Plus (10376)  
Ciba Corning ACS 180 Plus (10336)  
bioMerieux Vitek VIDAS (07806)  
ANALYTE: Triiodothyronine Uptake (T3U) (TU) (6120)

*TEST SYSTEM, ASSAY, EXAMINATION:*

Behring OPUS (07793)  
Chiron Diagnostics 550 Express (10352)  
Chiron Diagnostics ACS 180 (10375)  
Chiron Diagnostics ACS 180 Plus (10376)  
Ciba Corning ACS 180 Plus (10336)  
Dade Dimension AR (13421)  
Dade Dimension ES (13420)  
ANALYTE: Triiodothyronine, Free (FT3) (6121)

*TEST SYSTEM, ASSAY, EXAMINATION:*

Chiron Diagnostics ACS 180 (10375)  
Chiron Diagnostics ACS 180 Plus (10376)  
Ciba Corning ACS 180 Plus (10336)  
TOSOH A1A-1200 (61040)  
TOSOH A1A-1200DX (61154)  
TOSOH A1A-600 (61039)  
Technicon Immuno 1 System (61042)  
SPECIALITY/SUBSPECIALITY: General Chemistry  
ANALYTE: 5'Nucleotidase (0105)

*TEST SYSTEM, ASSAY, EXAMINATION:*

Chiron Diagnostics 550 Express (10352)  
ANALYTE: Acid Phosphatase (0407)  
*TEST SYSTEM, ASSAY, EXAMINATION:*

Chiron Diagnostics 550 Express (10352)  
Dade Dimension AR (13421)  
Dade Dimension ES (13420)  
Dade Dimension RxL (13436)  
Dade Dimension XL (13422)  
Dade aca Star (13423)  
ANALYTE: Alanine Aminotransferase (ALT) (SGPT) (0404)

*TEST SYSTEM, ASSAY, EXAMINATION:*

Chiron Diagnostics 550 Express (10352)  
Chiron Diagnostics 570 Alliance (10359)

Chiron Diagnostics 580 Alliance (10362)	(10352)	ANALYTE: Bilirubin, Neonatal (0705)
Dade Analyst (13425)	Chiron Diagnostics 570 Alliance (10359)	<i>TEST SYSTEM, ASSAY, EXAMINATION:</i>
Dade Dimension AR (13421)	Chiron Diagnostics 580 Alliance (10362)	Dade aca Star (13423)
Dade Dimension ES (13420)	Dade Analyst (13425)	ANALYTE: Bilirubin, Total (0706)
Dade Dimension RxL (13436)	Dade Dimension AR (13421)	<i>TEST SYSTEM, ASSAY, EXAMINATION:</i>
Dade Dimension XL (13422)	Dade Dimension ES (13420)	Chiron Diagnostics 550 Express (10352)
Dade aca Star (13423)	Dade Dimension RxL (13436)	Chiron Diagnostics 570 Alliance (10359)
ANALYTE: Albumin (0414)	Dade Dimension XL (13422)	Chiron Diagnostics 580 Alliance (10362)
<i>TEST SYSTEM, ASSAY, EXAMINATION:</i>	Dade aca Star (13423)	Dade Analyst (13425)
Chiron Diagnostics 550 Express (10352)	ANALYTE: Angiotensin Converting Enzyme (ACE) (0481)	Dade Dimension AR (13421)
Chiron Diagnostics 570 Alliance (10359)	<i>TEST SYSTEM, ASSAY, EXAMINATION:</i>	Dade Dimension ES (13420)
Chiron Diagnostics 580 Alliance (10362)	Chiron Diagnostics 550 Express (10352)	Dade Dimension RxL (13436)
Dade Dimension AR (13421)	ANALYTE: Apolipoprotein A1 (0462)	Dade Dimension XL (13422)
Dade Dimension ES (13420)	<i>TEST SYSTEM, ASSAY, EXAMINATION:</i>	Dade aca Star (13423)
Dade Dimension RxL (13436)	Chiron Diagnostics 550 Express (10352)	ANALYTE: Bilirubin, Urine (0738)
Dade Dimension XL (13422)	ANALYTE: Apolipoprotein B (0457)	<i>TEST SYSTEM, ASSAY, EXAMINATION:</i>
Dade aca Star (13423)	<i>TEST SYSTEM, ASSAY, EXAMINATION:</i>	Boehringer Mannheim Hitachi 717/ Chimera UA PERFECT (07780)
ANALYTE: Albumin, Urinary (0516)	Chiron Diagnostics 550 Express (10352)	ANALYTE: Blood Gases with pH (0708)
<i>TEST SYSTEM, ASSAY, EXAMINATION:</i>	ANALYTE: Aspartate Aminotransferase (AST) (SGOT) (0405)	<i>TEST SYSTEM, ASSAY, EXAMINATION:</i>
Dade aca Star (13423)	<i>TEST SYSTEM, ASSAY, EXAMINATION:</i>	AVL Compact 3 (04680)
ANALYTE: Alkaline Phosphatase (ALP) (0416)	Chiron Diagnostics 550 Express (10352)	Chiron Diagnostics 170 (10342)
<i>TEST SYSTEM, ASSAY, EXAMINATION:</i>	ANALYTE: Aspartate Aminotransferase (AST) (SGOT) (0405)	Chiron Diagnostics 178 (10343)
Chiron Diagnostics 550 Express (10352)	<i>TEST SYSTEM, ASSAY, EXAMINATION:</i>	Chiron Diagnostics 238 (10344)
Chiron Diagnostics 570 Alliance (10359)	Chiron Diagnostics 550 Express (10352)	Chiron Diagnostics 248 (10345)
Chiron Diagnostics 580 Alliance (10362)	Chiron Diagnostics 570 Alliance (10359)	Chiron Diagnostics 278 (10348)
Dade Analyst (13425)	Chiron Diagnostics 580 Alliance (10362)	Chiron Diagnostics 280 (10349)
Dade Dimension AR (13421)	Dade Analyst (13425)	Chiron Diagnostics 288 (10350)
Dade Dimension ES (13420)	Dade Dimension AR (13421)	Chiron Diagnostics 348 System (10337)
Dade Dimension RxL (13436)	Dade Dimension ES (13420)	Chiron Diagnostics 400 System (10338)
Dade Dimension XL (13422)	Dade Dimension RxL (13436)	Chiron Diagnostics 840 (10369)
Dade aca Star (13423)	Dade Dimension XL (13422)	Chiron Diagnostics 845 (10370)
ANALYTE: Alpha-Hydroxybutyrate Dehydrogenase (HBDH) (0419)	Dade aca Star (13423)	Chiron Diagnostics 850 (10371)
<i>TEST SYSTEM, ASSAY, EXAMINATION:</i>	ANALYTE: Beta-Hydroxybutyrate (0722)	Chiron Diagnostics 855 (10372)
Chiron Diagnostics 550 Express (10352)	<i>TEST SYSTEM, ASSAY, EXAMINATION:</i>	Chiron Diagnostics 860 (10373)
Dade aca Star (13423)	Chiron Diagnostics 550 Express (10352)	Chiron Diagnostics 865 (10374)
ANALYTE: Ammonia, Plasma/Serum (0427)	ANALYTE: Bilirubin, Direct (0704)	Instrumentation Laboratory IL Synthesis (28466)
<i>TEST SYSTEM, ASSAY, EXAMINATION:</i>	<i>TEST SYSTEM, ASSAY, EXAMINATION:</i>	Mallinckrodt Gem Premier Plus (40254)
Chiron Diagnostics 570 Alliance (10359)	Chiron Diagnostics 550 Express (10352)	ANALYTE: Calcium, Ionized (1004)
Dade Dimension AR (13421)	Chiron Diagnostics 570 Alliance (10359)	<i>TEST SYSTEM, ASSAY, EXAMINATION:</i>
Dade Dimension ES (13420)	Chiron Diagnostics 580 Alliance (10362)	AVL 9180 (04664)
Dade Dimension RxL (13436)	Dade Dimension AR (13421)	Chiron Diagnostics 288 (10350)
Dade Dimension XL (13422)	Dade Dimension ES (13420)	Chiron Diagnostics 348 System (10337)
Dade aca Star (13423)	Dade Dimension RxL (13436)	Chiron Diagnostics 400 System (10338)
ANALYTE: Amylase (0429)	Dade Dimension XL (13422)	Chiron Diagnostics 634 (10365)
<i>TEST SYSTEM, ASSAY, EXAMINATION:</i>	Dade aca Star (13423)	Chiron Diagnostics 850 (10371)
Chiron Diagnostics 550 Express		Chiron Diagnostics 855 (10372)
		Chiron Diagnostics 860 (10373)
		Chiron Diagnostics 865 (10374)
		Instrumentation Laboratory IL

Synthesis (28466)  
Mallinckrodt Gem Premier Plus  
(40254)

ANALYTE: Calcium, Total (1005)

TEST SYSTEM, ASSAY,  
EXAMINATION:

Chiron Diagnostics 550 Express  
(10352)

Chiron Diagnostics 570 Alliance  
(10359)

Chiron Diagnostics 580 Alliance  
(10362)

Dade Analyst (13425)

Dade Dimension AR (13421)

Dade Dimension ES (13420)

Dade Dimension RxL (13436)

Dade Dimension XL (13422)

Dade aca Star (13423)

ANALYTE: Carbon Dioxide, Total (CO2)  
(1003)

TEST SYSTEM, ASSAY,  
EXAMINATION:

Chiron Diagnostics 550 Express  
(10352)

Chiron Diagnostics 570 Alliance  
(10359)

Chiron Diagnostics 580 Alliance  
(10362)

Chiron Diagnostics 664 FAST 4  
(10368)

Dade Dimension AR (13421)

Dade Dimension ES (13420)

Dade Dimension RxL (13436)

Dade Dimension XL (13422)

Dade aca Star (13423)

ANALYTE: Cerebrospinal Fluid (CSF)  
Protein (1014)

TEST SYSTEM, ASSAY,  
EXAMINATION:

Dade Dimension AR (13421)

Dade Dimension ES (13420)

Dade Dimension RxL (13436)

Dade Dimension XL (13422)

Dade aca Star (13423)

ANALYTE: Chloride (1018)

TEST SYSTEM, ASSAY,  
EXAMINATION:

AVL 9180 (04664)

Chiron Diagnostics 288 (10350)

Chiron Diagnostics 400 System  
(10338)

Chiron Diagnostics 550 Express  
(10352)

Chiron Diagnostics 570 Alliance  
(10359)

Chiron Diagnostics 580 Alliance  
(10362)

Chiron Diagnostics 644 (10366)

Chiron Diagnostics 664 FAST 4  
(10368)

Chiron Diagnostics 850 (10371)

Chiron Diagnostics 855 (10372)

Chiron Diagnostics 860 (10373)

Chiron Diagnostics 865 (10374)

Dade Dimension AR (13421)

Dade Dimension ES (13420)

Dade Dimension RxL (13436)

Dade Dimension XL (13422)

Dade aca Star (13423)

Instrumentation Laboratory IL  
Synthesis (28466)

ANALYTE: Cholesterol (1020)

TEST SYSTEM, ASSAY,  
EXAMINATION:

Chiron Diagnostics 550 Express  
(10352)

Chiron Diagnostics 570 Alliance  
(10359)

Chiron Diagnostics 580 Alliance  
(10362)

Dade Analyst (13425)

Dade Dimension AR (13421)

Dade Dimension ES (13420)

Dade Dimension RxL (13436)

Dade Dimension XL (13422)

Dade aca Star (13423)

ANALYTE: Cholinesterase (1021)

TEST SYSTEM, ASSAY,  
EXAMINATION:

Chiron Diagnostics 550 Express  
(10352)

Roche Cobas Mira (55044)

Roche Cobas Mira S (55045)

ANALYTE: Cholyglycine (Bile Acids)  
(1053)

TEST SYSTEM, ASSAY,  
EXAMINATION:

Chiron Diagnostics 550 Express  
(10352)

ANALYTE: Creatine Kinase (CK) (1034)

TEST SYSTEM, ASSAY,  
EXAMINATION:

Behring OPUS (07793)

Behring OPUS Magnum (07794)

Behring OPUS Plus (07795)

Chiron Diagnostics 550 Express  
(10352)

Chiron Diagnostics 570 Alliance  
(10359)

Chiron Diagnostics 580 Alliance  
(10362)

Dade Dimension AR (13421)

Dade Dimension ES (13420)

Dade Dimension RxL (13436)

Dade Dimension XL (13422)

Dade aca Star (13423)

ANALYTE: Creatine Kinase MB  
Fraction (CKMB) (1002)

TEST SYSTEM, ASSAY,  
EXAMINATION:

Behring OPUS (07793)

Behring OPUS Magnum (07794)

Behring OPUS Plus (07795)

Boehringer Mannheim Elecsys 2010  
Analyzer (07810)

Chiron Diagnostics ACS 180 (10375)

Chiron Diagnostics ACS 180 Plus  
(10376)

Ciba Corning ACS 180 Plus (10336)

Dade Dimension AR (13421)

Dade Dimension ES (13420)

Dade Dimension RxL (13436)

Dade Dimension XL (13422)

Dade aca Star (13423)

Vitek Systems Vidas (67038)

bioMerieux Vitek VIDAS (07806)

ANALYTE: Creatinine (1035)

TEST SYSTEM, ASSAY,  
EXAMINATION:

Bayer DCA 2000+ Analyzer (07827)

Chiron Diagnostics 550 Express  
(10352)

Chiron Diagnostics 570 Alliance  
(10359)

Chiron Diagnostics 580 Alliance  
(10362)

Dade Analyst (13425)

Dade Dimension AR (13421)

Dade Dimension ES (13420)

Dade Dimension RxL (13436)

Dade Dimension XL (13422)

Dade aca Star (13423)

ANALYTE: Ferritin (1902)

TEST SYSTEM, ASSAY,  
EXAMINATION:

Behring OPUS (07793)

Chiron Diagnostics ACS 180 (10375)

Chiron Diagnostics ACS 180 Plus  
(10376)

Ciba Corning ACS 180 Plus (10336)

Dade aca Star with aca plus

Immunoassay System (13424)

Roche Cobas INTEGRA (55179)

bioMerieux Vitek VIDAS (07806)

ANALYTE: Folate (Folic acid) (1907)

TEST SYSTEM, ASSAY,  
EXAMINATION:

Chiron Diagnostics ACS 180 (10375)

Chiron Diagnostics ACS 180 Plus  
(10376)

Ciba Corning ACS 180 Plus (10336)

TOSOH A1A-1200 (61040)

TOSOH A1A-1200DX (61154)

TOSOH A1A-600 (61039)

ANALYTE: Folate, Red Blood Cell (RBC)  
Folate) (1930)

TEST SYSTEM, ASSAY,  
EXAMINATION:

Chiron Diagnostics ACS 180 (10375)

Chiron Diagnostics ACS 180 Plus  
(10376)

Ciba Corning ACS 180 Plus (10336)

ANALYTE: Fructosamine (1914)

TEST SYSTEM, ASSAY,  
EXAMINATION:

Beckman Synchron CX 4 (07071)

Beckman Synchron CX 4 CE (07174)

Beckman Synchron CX 5 (07072)

Beckman Synchron CX 5 CE (07491)

Beckman Synchron CX 7 (07073)

ANALYTE: Gamma Glutamyl  
Transferase (GGT) (2201)

TEST SYSTEM, ASSAY,  
EXAMINATION:

Chiron Diagnostics 550 Express

(10352)  
Chiron Diagnostics 570 Alliance  
(10359)  
Chiron Diagnostics 580 Alliance  
(10362)  
Dade Analyst (13425)  
Dade Dimension AR (13421)  
Dade Dimension ES (13420)  
Dade Dimension RxL (13436)  
Dade Dimension XL (13422)  
Dade aca Star (13423)  
ANALYTE: Glucose (2203)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

Chiron Diagnostics 400 System  
(10338)  
Chiron Diagnostics 550 Express  
(10352)  
Chiron Diagnostics 570 Alliance  
(10359)  
Chiron Diagnostics 580 Alliance  
(10362)  
Chiron Diagnostics 860 (10373)  
Chiron Diagnostics 865 (10374)  
Dade Analyst (13425)  
Dade Dimension AR (13421)  
Dade Dimension ES (13420)  
Dade Dimension RxL (13436)  
Dade Dimension XL (13422)  
Dade aca Star (13423)  
Instrumentation Laboratory IL  
Synthesis (28466)  
ANALYTE: Glucose, Urine (2225)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

Boehringer Mannheim Hitachi 717/  
Chimera UA PERFECT (07780)  
ANALYTE: Glucose-6-Phosphate  
Dehydrogenase (G-6-PDH) (2208)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

Chiron Diagnostics 550 Express  
(10352)  
ANALYTE: Glycosylated Hemoglobin  
(Hgb A1C) (2204)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

Bio-Rad DiaSTAT Analyzer (07817)  
Chiron Diagnostics Model 765  
Glycomat (10380)  
Roche Cobas INTEGRA (55179)  
Technicon OPERA Clinical Chemistry  
System (61161)  
Technicon RA 1000 (61010)  
Technicon RA 2000 (61011)  
Technicon RA 500 (61012)  
Technicon RA XT (61013)  
ANALYTE: HDL Cholesterol (2550)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

Boehringer Mannheim Hitachi 704/  
BM Direct HDL (07818)  
Boehringer Mannheim Hitachi 717/  
BM Direct HDL (07819)

Boehringer Mannheim Hitachi 717/  
Genzyme N-geneous HDL (07812)  
Boehringer Mannheim Hitachi 736/  
Genzyme N-geneous HDL (07813)  
Boehringer Mannheim Hitachi 747/  
BM Direct HDL (07820)  
Boehringer Mannheim Hitachi 747/  
Genzyme N-geneous HDL (07814)  
Boehringer Mannheim Hitachi 911/  
BM Direct HDL (07821)  
Boehringer Mannheim Hitachi 911/  
Genzyme N-geneous HDL (07811)  
Boehringer Mannheim Hitachi 914/  
BM Direct HDL (07822)  
Boehringer Mannheim Hitachi 917/  
BM Direct HDL (07823)  
Boehringer Mannheim Hitachi 917/  
Genzyme N-geneous HDL (07815)  
Chiron Diagnostics 550 Express (DMA  
One Shots) (10353)  
Chiron Diagnostics 550 Express (MHS  
SPINPRO) (10355)  
Chiron Diagnostics 550 Express (Ref  
Diag Magnetic HDL Sep) (10356)  
Chiron Diagnostics 550 Express  
(Sigma ISOSPIN) (10357)  
Chiron Diagnostics 550 Express (T-  
Am. Singles) (10358)  
Chiron Diagnostics 570 Alliance  
(MHS SPINPRO) (10360)  
Chiron Diagnostics 570 Alliance  
(Sigma ISOSPIN) (10361)  
Chiron Diagnostics 580 Alliance  
(MHS SPINPRO) (10363)  
Dade Analyst (13425)  
Olympus AU 5200/Genzyme N-  
geneous HDL (46223)  
Olympus AU 800/Genzyme N-  
geneous HDL (46222)  
Roche Cobas FARA/Genzyme N-  
geneous HDL (55213)  
Roche Cobas Mira/Genzyme N-  
geneous HDL (55212)  
Technicon DAX 96/Genzyme N-  
geneous HDL (61259)  
ANALYTE: Haptoglobin (2511)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

Beckman IMMAGE Immunochemistry  
System (07816)  
Chiron Diagnostics 550 Express  
(10352)  
ANALYTE: Hemoglobin A2 (2535)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

Chiron Diagnostics Model 765  
Glycomat (10380)  
ANALYTE: Hemoglobin Barts (2537)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

Bio-Rad Variant/Alpha Thalassemia  
Short Program (07791)  
ANALYTE: Hemoglobin Fractions  
(2544)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

Chiron Diagnostics Model 765

Glycomat (10380)  
ANALYTE: Hemoglobin S (2536)  
*TEST SYSTEM, ASSAY,  
EXAMINATION:*

SA Scientific SAS Sickle Cell Test  
(58420)  
ANALYTE: Iron (2814)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

Chiron Diagnostics 550 Express  
(10352)  
Chiron Diagnostics 570 Alliance  
(10359)  
Dade Dimension AR (13421)  
Dade Dimension ES (13420)  
Dade Dimension RxL (13436)  
Dade Dimension XL (13422)  
Dade aca Star (13423)  
ANALYTE: Iron Binding Capacity,  
Unsat. (UIBC) no pretreat. (2823)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

Abbott Spectrum (04067)  
Abbott Spectrum EPX (04068)  
Abbott Spectrum Series II (04069)  
Beckman Synchron CX 3 (07070)  
Beckman Synchron CX 4 (07071)  
Beckman Synchron CX 4 CE (07174)  
Beckman Synchron CX 4 Delta  
(07762)  
Beckman Synchron CX 5 (07072)  
Beckman Synchron CX 5 CE (07491)  
Beckman Synchron CX 5 Delta  
(07763)  
Beckman Synchron CX 7 (07073)  
Beckman Synchron CX 7 Delta  
(07764)  
Chiron Diagnostics 550 Express  
(10352)  
Ciba Corning 550 Express (10038)  
Coulter Optichem 100 (10115)  
Coulter Optichem 120 (10079)  
Coulter Optichem 180 (10080)  
Instrumentation Laboratory IL  
Monarch 1000 (28082)  
Instrumentation Laboratory IL  
Monarch 2000 (28231)  
Instrumentation Laboratory IL  
Monarch Plus (28083)  
Olympus Reply (46089)  
Technicon RA 1000 (61010)  
Technicon RA 500 (61012)  
Technicon RA XT (61013)  
ANALYTE: Ketone, Urine (3404)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

Boehringer Mannheim Hitachi 717/  
Chimera UA PERFECT (07780)  
ANALYTE: LDL Cholesterol (3748)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

Chiron Diagnostics 550 Express  
(Genzyme immunosep tube) (10354)  
ANALYTE: Lactate Dehydrogenase  
(LDH) (3701)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

Chiron Diagnostics 550 Express (10352)  
Chiron Diagnostics 570 Alliance (10359)  
Chiron Diagnostics 580 Alliance (10362)  
Dade Dimension AR (13421)  
Dade Dimension ES (13420)  
Dade Dimension RxL (13436)  
Dade Dimension XL (13422)  
Dade aca Star (13423)  
ANALYTE: Lactate Dehydrogenase Heart Fraction (LDH-1) (3702)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

Chiron Diagnostics 550 Express (10352)  
Dade aca Star (13423)  
ANALYTE: Lactate Dehydrogenase Liver Fraction (LLDH) (3703)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

Dade aca Star (13423)  
ANALYTE: Lactic Acid (Lactate) (3704)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

Chiron Diagnostics 550 Express (10352)  
Chiron Diagnostics 570 Alliance (10359)  
Chiron Diagnostics 860 (10373)  
Chiron Diagnostics 865 (10374)  
Dade Dimension AR (13421)  
Dade Dimension ES (13420)  
Dade Dimension RxL (13436)  
Dade Dimension XL (13422)  
Dade aca Star (13423)  
ANALYTE: Lipase (3711)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

Chiron Diagnostics 550 Express (10352)  
Chiron Diagnostics 570 Alliance (10359)  
Dade Dimension AR (13421)  
Dade Dimension ES (13420)  
Dade Dimension RxL (13436)  
Dade Dimension XL (13422)  
Dade aca Star (13423)  
ANALYTE: Magnesium (4002)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

Chiron Diagnostics 550 Express (10352)  
Chiron Diagnostics 570 Alliance (10359)  
Chiron Diagnostics 580 Alliance (10362)  
Dade Dimension AR (13421)  
Dade Dimension ES (13420)  
Dade Dimension RxL (13436)  
Dade Dimension XL (13422)

Dade aca Star (13423)  
ANALYTE: Methemoglobin (4032)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

A-VOX Systems AVOXimeter 4000 (04678)  
Chiron Diagnostics 845 (10370)  
Chiron Diagnostics 855 (10372)  
Chiron Diagnostics 865 (10374)  
Instrumentation Laboratory IL Synthesis (28466)  
ANALYTE: Microalbumin (4019)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

Bayer DCA 2000+ Analyzer (07827)  
Chiron Diagnostics 550 Express (10352)  
ANALYTE: Microprotein, CSF (4026)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

Chiron Diagnostics 550 Express (10352)  
ANALYTE: Microprotein, Urine (4027)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

Chiron Diagnostics 550 Express (10352)  
ANALYTE: Myoglobin (4023)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

Behring OPUS (07793)  
Roche Cobas INTEGRA (55179)  
Technicon Immuno 1 System (61042)  
ANALYTE: Nitrite, Urine (4318)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

Boehringer Mannheim Hitachi 717/ Chimera UA PERFECT (07780)  
ANALYTE: Osmolality, Serum (4602)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

Advanced Instruments Micro Osmometer Model 3300 (04671)  
ANALYTE: Osmolality, Urine (4603)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

Advanced Instruments Micro Osmometer Model 3300 (04671)  
ANALYTE: Oxyhemoglobin/Oxygen Saturation (4604)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

A-VOX Systems AVOXimeter 4000 (04678)  
Chiron Diagnostics 2500 CO-oximeter (10346)  
Chiron Diagnostics 270 CO-oximeter (10347)  
Chiron Diagnostics 845 (10370)  
Chiron Diagnostics 855 (10372)  
Chiron Diagnostics 865 (10374)

Instrumentation Laboratory IL Synthesis (28466)  
ANALYTE: Phenylalanine (4942)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

Bio-Rad RADIAS System (07493)  
ANALYTE: Phosphorus (4906)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

Chiron Diagnostics 550 Express (10352)  
Chiron Diagnostics 570 Alliance (10359)  
Chiron Diagnostics 580 Alliance (10362)  
Dade Dimension AR (13421)  
Dade Dimension ES (13420)  
Dade Dimension RxL (13436)  
Dade Dimension XL (13422)  
Dade aca Star (13423)  
ANALYTE: Potassium (4910)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

AVL 9180 (04664)  
Chiron Diagnostics 288 (10350)  
Chiron Diagnostics 348 System (10337)  
Chiron Diagnostics 400 System (10338)  
Chiron Diagnostics 480 (10351)  
Chiron Diagnostics 570 Alliance (10359)  
Chiron Diagnostics 580 Alliance (10362)  
Chiron Diagnostics 614 (10364)  
Chiron Diagnostics 644 (10366)  
Chiron Diagnostics 654 (10367)  
Chiron Diagnostics 664 FAST 4 (10368)

Chiron Diagnostics 850 (10371)  
Chiron Diagnostics 855 (10372)  
Chiron Diagnostics 860 (10373)  
Chiron Diagnostics 865 (10374)  
Dade Dimension AR (13421)  
Dade Dimension ES (13420)  
Dade Dimension RxL (13436)  
Dade Dimension XL (13422)  
Instrumentation Laboratory IL Synthesis (28466)  
Mallinckrodt Gem Premier Plus (40254)  
Medica EasyStat Na/K/Li Analyzer (40256)

ANALYTE: Prealbumin (4911)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

Chiron Diagnostics 550 Express (10352)  
ANALYTE: Prostatic Specific Antigen (PSA) (4919)  
*TEST SYSTEM, ASSAY,  
EXAMINATION:*  
Dade aca Star with aca plus Immunoassay System (13424)

- Du Pont ACA III with aca plus Immunoassay System (13253)  
 Du Pont ACA IV with aca plus Immunoassay System (13254)  
 Du Pont ACA Star with aca plus Immunoassay System (13358)  
 Du Pont ACA V with aca plus Immunoassay System (13255)  
 ANALYTE: Protein Fractions (4920)  
*TEST SYSTEM, ASSAY, EXAMINATION:*  
 Beckman Paragon CZE 2000 (07725)  
 ANALYTE: Protein, Total (4921)  
*TEST SYSTEM, ASSAY, EXAMINATION:*  
 Chiron Diagnostics 550 Express (10352)  
 Chiron Diagnostics 570 Alliance (10359)  
 Chiron Diagnostics 580 Alliance (10362)  
 Dade Analyst (13425)  
 Dade Dimension AR (13421)  
 Dade Dimension ES (13420)  
 Dade Dimension RxL (13436)  
 Dade Dimension XL (13422)  
 Dade aca Star (13423)  
 ANALYTE: Protein, Total (urine) (4972)  
*TEST SYSTEM, ASSAY, EXAMINATION:*  
 Boehringer Mannheim Hitachi 717/ Chimera UA PERFECT (07780)  
 Boehringer Mannheim Hitachi 747/ STC AutoLite (07785)  
 Dade Dimension AR (13421)  
 Dade Dimension ES (13420)  
 Dade Dimension RxL (13436)  
 Dade Dimension XL (13422)  
 Dade aca Star (13423)  
 ANALYTE: Pseudocholinesterase (4923)  
*TEST SYSTEM, ASSAY, EXAMINATION:*  
 Dade Dimension AR (13421)  
 Dade Dimension ES (13420)  
 Dade Dimension RxL (13436)  
 Dade Dimension XL (13422)  
 Dade aca Star (13423)  
 ANALYTE: Reduced Hemoglobin (Deoxyhemoglobin) (5523)  
*TEST SYSTEM, ASSAY, EXAMINATION:*  
 Chiron Diagnostics 845 (10370)  
 Chiron Diagnostics 855 (10372)  
 Chiron Diagnostics 865 (10374)  
 Instrumentation Laboratory IL Synthesis (28466)  
 ANALYTE: Sodium (5805)  
*TEST SYSTEM, ASSAY, EXAMINATION:*  
 AVL 9180 (04664)  
 Chiron Diagnostics 288 (10350)  
 Chiron Diagnostics 348 System (10337)  
 Chiron Diagnostics 400 System (10338)  
 Chiron Diagnostics 480 (10351)  
 Chiron Diagnostics 570 Alliance (10359)  
 Chiron Diagnostics 580 Alliance (10362)  
 Chiron Diagnostics 614 (10364)  
 Chiron Diagnostics 644 (10366)  
 Chiron Diagnostics 654 (10367)  
 Chiron Diagnostics 664 FAST 4 (10368)  
 Chiron Diagnostics 850 (10371)  
 Chiron Diagnostics 855 (10372)  
 Chiron Diagnostics 860 (10373)  
 Chiron Diagnostics 865 (10374)  
 Dade Dimension AR (13421)  
 Dade Dimension ES (13420)  
 Dade Dimension RxL (13436)  
 Dade Dimension XL (13422)  
 Instrumentation Laboratory IL Synthesis (28466)  
 Mallinckrodt Gem Premier Plus (40254)  
 Medica EasyStat Na/K/Li Analyzer (40256)  
 ANALYTE: Sorbital Dehydrogenase (SDH) (5823)  
*TEST SYSTEM, ASSAY, EXAMINATION:*  
 Chiron Diagnostics 550 Express (10352)  
 ANALYTE: Transferrin (6114)  
*TEST SYSTEM, ASSAY, EXAMINATION:*  
 Beckman IMAGE Immunochemistry System (07816)  
 Chiron Diagnostics 550 Express (10352)  
 ANALYTE: Triglyceride (6118)  
*TEST SYSTEM, ASSAY, EXAMINATION:*  
 Chiron Diagnostics 550 Express (10352)  
 Chiron Diagnostics 570 Alliance (10359)  
 Chiron Diagnostics 580 Alliance (10362)  
 Dade Analyst (13425)  
 Dade Dimension AR (13421)  
 Dade Dimension ES (13420)  
 Dade Dimension RxL (13436)  
 Dade Dimension XL (13422)  
 Dade aca Star (13423)  
 ANALYTE: Troponin T (Tn T) (6140)  
*TEST SYSTEM, ASSAY, EXAMINATION:*  
 Boehringer Mannheim Elecsys 2010 Analyzer (07810)  
 ANALYTE: Urea (BUN) (6403)  
*TEST SYSTEM, ASSAY, EXAMINATION:*  
 Chiron Diagnostics 550 Express (10352)  
 Chiron Diagnostics 570 Alliance (10359)  
 Chiron Diagnostics 580 Alliance (10362)  
 Dade Analyst (13425)  
 Dade Dimension AR (13421)  
 Dade Dimension ES (13420)  
 Dade Dimension RxL (13436)  
 Dade Dimension XL (13422)  
 Dade aca Star (13423)  
 ANALYTE: Urobilinogen, Urine (6413)  
*TEST SYSTEM, ASSAY, EXAMINATION:*  
 Boehringer Mannheim Hitachi 717/ Chimera UA PERFECT (07780)  
 ANALYTE: Vitamin B12 (6707)  
*TEST SYSTEM, ASSAY, EXAMINATION:*  
 Behring OPUS (07793)  
 Behring OPUS Magnum (07794)  
 Behring OPUS Plus (07795)  
 Chiron Diagnostics ACS 180 (10375)  
 Chiron Diagnostics ACS 180 Plus (10376)  
 Ciba Corning ACS 180 Plus (10336)  
 ANALYTE: pH, Urine (4978)  
*TEST SYSTEM, ASSAY, EXAMINATION:*  
 Boehringer Mannheim Hitachi 717/ Chimera UA PERFECT (07780)  
 SPECIALITY/SUBSPECIALITY: General Immunology  
 ANALYTE: Allergen specific IgE (0417)  
*TEST SYSTEM, ASSAY, EXAMINATION:*  
 Pharmacia UniCAP 100 (49164)  
 ANALYTE: Alpha-1-Antitrypsin (0421)  
*TEST SYSTEM, ASSAY, EXAMINATION:*  
 Chiron Diagnostics 550 Express (10352)  
 ANALYTE: Beta-2 microglobulin (0703)  
*TEST SYSTEM, ASSAY, EXAMINATION:*  
 Behring Nephelometer (07273)  
 Behring Nephelometer 100 (07272)  
 Chiron Diagnostics 570 Alliance (10359)  
 Chiron Diagnostics 580 Alliance (10362)  
 Dade Analyst (13425)  
 Dade Dimension AR (13421)  
 Dade Dimension ES (13420)  
 Dade Dimension RxL (13436)  
 Dade Dimension XL (13422)  
 Dade aca Star (13423)  
 ANALYTE: Uric Acid (6404)  
*TEST SYSTEM, ASSAY, EXAMINATION:*  
 Abbott Bichromatic ABA 200 (04036)  
 Chiron Diagnostics 550 Express (10352)  
 Chiron Diagnostics 570 Alliance (10359)  
 Chiron Diagnostics 580 Alliance (10362)  
 Dade Analyst (13425)  
 Dade Dimension AR (13421)  
 Dade Dimension ES (13420)  
 Dade Dimension RxL (13436)  
 Dade Dimension XL (13422)  
 Dade aca Star (13423)  
 ANALYTE: Urobilinogen, Urine (6413)  
*TEST SYSTEM, ASSAY, EXAMINATION:*  
 Boehringer Mannheim Hitachi 717/ Chimera UA PERFECT (07780)  
 ANALYTE: Vitamin B12 (6707)  
*TEST SYSTEM, ASSAY, EXAMINATION:*  
 Behring OPUS (07793)  
 Behring OPUS Magnum (07794)  
 Behring OPUS Plus (07795)  
 Chiron Diagnostics ACS 180 (10375)  
 Chiron Diagnostics ACS 180 Plus (10376)  
 Ciba Corning ACS 180 Plus (10336)  
 ANALYTE: pH, Urine (4978)  
*TEST SYSTEM, ASSAY, EXAMINATION:*  
 Boehringer Mannheim Hitachi 717/ Chimera UA PERFECT (07780)  
 SPECIALITY/SUBSPECIALITY: General Immunology  
 ANALYTE: Allergen specific IgE (0417)  
*TEST SYSTEM, ASSAY, EXAMINATION:*  
 Pharmacia UniCAP 100 (49164)  
 ANALYTE: Alpha-1-Antitrypsin (0421)  
*TEST SYSTEM, ASSAY, EXAMINATION:*  
 Chiron Diagnostics 550 Express (10352)  
 ANALYTE: Beta-2 microglobulin (0703)  
*TEST SYSTEM, ASSAY, EXAMINATION:*  
 Behring Nephelometer (07273)  
 Behring Nephelometer 100 (07272)



Behring Nephelometer II (07563)  
 Dade aca Star (13423)  
 Roche Cobas Bio with DENS  
 (automated data reduction) (55208)  
 Roche Cobas FARA (55040)  
 Roche Cobas Mira (55044)  
 ANALYTE: C-Reactive Protein (CRP)  
 (1001)

*TEST SYSTEM, ASSAY,  
 EXAMINATION:*

Beckman IMMAGE Immunochemistry  
 System (07816)  
 Chiron Diagnostics 550 Express  
 (10352)  
 Dade Dimension AR (13421)  
 Dade Dimension ES (13420)  
 Dade Dimension RxL (13436)  
 Dade Dimension XL (13422)  
 Dade aca Star (13423)  
 ANALYTE: C1-Esterase Inhibitor  
 (C1INH) (1051)

*TEST SYSTEM, ASSAY,  
 EXAMINATION:*

Behring Nephelometer (07273)  
 Behring Nephelometer 100 (07272)  
 Behring Nephelometer II (07563)  
 ANALYTE: CD4 positive Lymphocytes  
 (1116)

*TEST SYSTEM, ASSAY,  
 EXAMINATION:*

Coulter STKS (10093)  
 ANALYTE: CD8 positive Lymphocytes  
 (1118)

*TEST SYSTEM, ASSAY,  
 EXAMINATION:*

Coulter STKS (10093)  
 ANALYTE: Complement C3 (1029)

*TEST SYSTEM, ASSAY,  
 EXAMINATION:*

Chiron Diagnostics 550 Express  
 (10352)  
 Instrumentation Laboratory ILAB  
 1800 (28323)  
 Instrumentation Laboratory ILAB 900  
 (28322)  
 ANALYTE: Complement C4 (1030)

*TEST SYSTEM, ASSAY,  
 EXAMINATION:*

Chiron Diagnostics 550 Express  
 (10352)  
 Instrumentation Laboratory ILAB  
 1800 (28323)  
 Instrumentation Laboratory ILAB 900  
 (28322)  
 ANALYTE: Cytomegalovirus Antibodies  
 (1039)

*TEST SYSTEM, ASSAY,  
 EXAMINATION:*

Abbott AxSYM CMV IgG (04628)  
 Cirrus Diagnostics Immulite (10159)  
 Quest SeraQuest CMV IgG/Hyperion  
 HyPrep Plus (auto. calc.) (52048)

Sienna Biotech Copalis One  
 Immunoassay Sys/CMV Total Ab  
 (58418)  
 Sienna Biotech Copalis One  
 Immunoassay Sys/ToRC Total Ab  
 (58415)  
 bioMerieux Vitek VIDAS (07806)  
 ANALYTE: Helicobacter pylori  
 Antibodies (2513)

*TEST SYSTEM, ASSAY,  
 EXAMINATION:*

Abbott FlexPack HP Test (04673)  
 ANALYTE: Herpes simplex I and/or II  
 Antibodies (2530)

*TEST SYSTEM, ASSAY,  
 EXAMINATION:*

Cirrus Diagnostics Immulite (10159)  
 ANALYTE: Immunoglobulins—  
 monoclonal/polyclonal (2802)

*TEST SYSTEM, ASSAY,  
 EXAMINATION:*

Beckman Paragon CZE 2000 (07725)  
 ANALYTE: Immunoglobulins IgA  
 (2803)

*TEST SYSTEM, ASSAY,  
 EXAMINATION:*

Chiron Diagnostics 550 Express  
 (10352)  
 Dade aca Star (13423)  
 Instrumentation Laboratory ILAB  
 1800 (28323)  
 Instrumentation Laboratory ILAB 900  
 (28322)  
 ANALYTE: Immunoglobulins IgE (2805)

*TEST SYSTEM, ASSAY,  
 EXAMINATION:*

Chiron Diagnostics ACS 180 (10375)  
 Chiron Diagnostics ACS 180 Plus  
 (10376)  
 Ciba Corning ACS 180 Plus (10336)  
 bioMerieux Vitek VIDAS (07806)  
 ANALYTE: Immunoglobulins IgG (2806)

*TEST SYSTEM, ASSAY,  
 EXAMINATION:*

Chiron Diagnostics 550 Express  
 (10352)  
 Dade aca Star (13423)  
 Instrumentation Laboratory ILAB  
 1800 (28323)  
 Instrumentation Laboratory ILAB 900  
 (28322)  
 ANALYTE: Immunoglobulins IgM  
 (2808)

*TEST SYSTEM, ASSAY,  
 EXAMINATION:*

Chiron Diagnostics 550 Express  
 (10352)  
 Dade aca Star (13423)  
 Instrumentation Laboratory ILAB  
 1800 (28323)  
 Instrumentation Laboratory ILAB 900  
 (28322)

ANALYTE: Lyme Disease Antibodies  
 (Borrelia burgdorferi Abs) (3714)

*TEST SYSTEM, ASSAY,  
 EXAMINATION:*

Remel Rapidot Lyme Disease (B.  
 burgdorferi IgG/IgM Abs) (55219)  
 bioMerieux Vitek VIDAS (07806)  
 ANALYTE: Mumps Antibodies (4007)

*TEST SYSTEM, ASSAY,  
 EXAMINATION:*

bioMerieux Vitek VIDAS (07806)  
 ANALYTE: Mycoplasma pneumoniae  
 Antibodies (4016)

*TEST SYSTEM, ASSAY,  
 EXAMINATION:*

Remel Mycoplasma pneumonia IgG/  
 IgM (55214)  
 ANALYTE: Rheumatoid Factor (RF)  
 (5508)

*TEST SYSTEM, ASSAY,  
 EXAMINATION:*

Beckman IMMAGE Immunochemistry  
 System (07816)  
 Randox Laboratories RF Latex Test  
 (55209)  
 Roche Cobas INTEGRA (55179)  
 ANALYTE: Rubella Antibodies (5510)

*TEST SYSTEM, ASSAY,  
 EXAMINATION:*

Abbott AxSYM Rubella IgG (04629)  
 Behring OPUS (07793)  
 Murex Rub-ex Latex Agglutination  
 (40243)  
 Quest SeraQuest Rubella IgG/  
 Hyperion HyPrep Plus (auto calc)  
 (52039)

Sienna Biotech Copalis One  
 Immunoassay Sys/Rubella Total Ab  
 (58417)

Sienna Biotech Copalis One  
 Immunoassay Sys/ToRC Total Ab  
 (58415)  
 bioMerieux Vitek VIDAS (07806)  
 ANALYTE: Rubeola Antibodies  
 (measles) (5511)

*TEST SYSTEM, ASSAY,  
 EXAMINATION:*

bioMerieux Vitek VIDAS (07806)  
 ANALYTE: Toxoplasma gondii  
 Antibodies (6113)

*TEST SYSTEM, ASSAY,  
 EXAMINATION:*

Abbott AxSYM Toxo IgG (04645)  
 Abbott AxSYM Toxo IgM (04640)  
 Behring OPUS (07793)  
 Quest SeraQuest Toxo IgG/Hyperion  
 HyPrep Plus (auto calc) (52045)  
 Sienna Biotech Copalis One  
 Immunoassay Sys/ToRC Total Ab  
 (58415)  
 Sienna Biotech Copalis One  
 Immunoassay Sys/Toxo Total Ab

(58416)  
Technicon Immuno 1 System (61042)  
bioMerieux Vitek VIDAS (07806)  
ANALYTE: Troponin-I (Cardiac) (6153)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

Behring OPUS (07793)  
Behring OPUS Magnum (07794)  
Behring OPUS Plus (07795)  
ANALYTE: Varicella-Zoster Virus  
Antibodies (6704)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

bioMerieux Vitek VIDAS (07806)  
SPECIALITY/SUBSPECIALITY:  
Hematology  
ANALYTE: Activated Clotting Time  
(ACT) (0461)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

International Technidyne Hemochron  
Jr. Low Range ACT (28464)  
ANALYTE: Activated Partial  
Thromboplastin Time (APTT)  
(0409)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

American Bioproducts STA Compact  
Analyzer (04677)  
Behring Coagulation Timer (BCT)  
(07824)  
Instrumentation Laboratory IL ACL  
6000 (28454)  
Sigma Diagnostics Amelung AMAX  
CS-190 (auto dilution) (58413)  
Sigma Diagnostics Amelung KC 1 A  
Coagulation Analyzer (58411)  
Sigma Diagnostics Amelung KC 4 A  
Micro Coagulation Analyzer (58412)  
ANALYTE: Antithrombin III (ATIII)  
(0456)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

Dade aca Star (13423)  
Roche Cobas INTEGRA (55179)  
ANALYTE: Fibrin Split Products (Fibrin  
Degradation) (1904)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

Dade aca Star (13423)  
ANALYTE: Fibrinogen (1905)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

American Bioproducts STA Compact  
Analyzer (04677)  
Behring Coagulation Timer (BCT)  
(07824)  
Chiron Diagnostics 550 Express  
(10352)  
Dade aca Star (13423)  
Instrumentation Laboratory IL ACL  
6000 (28454)

Sigma Diagnostics Amelung AMAX  
CS-190 (auto dilution) (58413)  
Sigma Diagnostics Amelung AMAX  
CS-190 (manual dilution) (58414)  
ANALYTE: Hematocrit (2514)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

Array Medical Ichor (04670)  
Becton Dickinson QBC AUTOREAD  
System with QBC AccuTube  
(07784)  
Chiron Diagnostics 348 System  
(10337)  
Chiron Diagnostics 400 System  
(10338)  
Coulter GEN-S System (10381)  
Danam EXCELL 16 (13430)  
Infolab EXCELL 16 (28457)  
Instrumentation Laboratory IL  
Synthesis (28466)  
Mallinckrodt Gem Premier Plus  
(40254)

Swelab Instrument AB AutoCounter  
(58402)

ANALYTE: Hemoglobin (2515)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

A-VOX Systems AVOXimeter 4000  
(04678)  
Array Medical Ichor (04670)  
Becton Dickinson QBC AUTOREAD  
System with QBC AccuTube  
(07784)  
Chiron Diagnostics 280 (10349)  
Chiron Diagnostics 288 (10350)  
Chiron Diagnostics 845 (10370)  
Chiron Diagnostics 855 (10372)  
Chiron Diagnostics 865 (10374)  
Coulter GEN-S System (10381)  
Danam EXCELL 16 (13430)  
Infolab EXCELL 16 (28457)  
Instrumentation Laboratory IL  
Synthesis (28466)  
Swelab Instrument AB AutoCounter  
(58402)  
Technicon opera (61161)

ANALYTE: Heparin (2518)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

Dade aca Star (13423)  
ANALYTE: Plasminogen (4907)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

Dade aca Star (13423)  
ANALYTE: Platelet Activated Clot Ratio  
(4977)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

HemoTec Hepcon/HMS (Platelet  
Function Test-PAF) (25260)  
ANALYTE: Platelet Aggregation (4928)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

Chrono-log Whole Blood

Aggregometer (10339)  
ANALYTE: Platelet Count (4908)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

Array Medical Ichor (04670)  
Becton Dickinson QBC AUTOREAD  
System with QBC AccuTube  
(07784)  
Coulter GEN-S System (10381)  
Danam EXCELL 16 (13430)  
Infolab EXCELL 16 (28457)  
Swelab Instrument AB AutoCounter  
(58402)

ANALYTE: Prothrombin Time (PT)  
(4922)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

American Bioproducts STA Compact  
Analyzer (04677)  
Behring Coagulation Timer (BCT)  
(07824)  
Instrumentation Laboratory IL ACL  
6000 (28454)  
Sigma Diagnostics Amelung AMAX  
CS-190 (auto dilution) (58413)  
Sigma Diagnostics Amelung KC 1 A  
Coagulation Analyzer (58411)  
Sigma Diagnostics Amelung KC 4 A  
Micro Coagulation Analyzer (58412)  
ANALYTE: Red Blood Cell Count  
(Erythrocyte Count) (RBC) (5502)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

Array Medical Ichor (04670)  
Coulter GEN-S System (10381)  
Danam EXCELL 16 (13430)  
Infolab EXCELL 16 (28457)  
Swelab Instrument AB AutoCounter  
(58402)

ANALYTE: Reptilase Time (5521)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

Behring Coagulation Timer (BCT)  
(07824)  
Sigma Diagnostics Amelung AMAX  
CS-190 (auto dilution) (58413)  
Sigma Diagnostics Amelung KC 4 A  
Micro Coagulation Analyzer (58412)  
ANALYTE: Reticulocyte Count (5506)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

Coulter GEN-S System (10381)  
IMI MICRO21 with Retic (28448)  
ANALYTE: Thrombin Time (6105)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

American Bioproducts STA Compact  
Analyzer (04677)  
Sigma Diagnostics Amelung AMAX  
CS-190 (auto dilution) (58413)  
Sigma Diagnostics Amelung KC 4 A  
Micro Coagulation Analyzer (58412)  
ANALYTE: White Blood Cell Count  
(Leukocyte Count) (WBC) (7002)

**TEST SYSTEM, ASSAY,  
EXAMINATION:**

Array Medical Ichor (04670)  
Becton Dickinson QBC AUTOREAD  
System with QBC AccuTube  
(07784)  
Coulter GEN-S System (10381)  
Danam EXCELL 16 (13430)  
Infolab EXCELL 16 (28457)  
Swelab Instrument AB AutoCounter  
(58402)  
ANALYTE: White Blood Cell  
Differential (WBC Diff) (7001)

**TEST SYSTEM, ASSAY,  
EXAMINATION:**

Becton Dickinson QBC AUTOREAD  
System with QBC AccuTube  
(07784)  
Coulter GEN-S System (10381)  
Danam EXCELL 16 (13430)  
IMI MICRO21 (no interpret. atypical/  
immature cells) (28446)  
Infolab EXCELL 16 (28457)  
Swelab Instrument AB AutoCounter  
(58402)  
SPECIALITY/SUBSPECIALITY:  
Toxicology / TDM  
ANALYTE: Acetaminophen (0406)

**TEST SYSTEM, ASSAY,  
EXAMINATION:**

Beckman Synchron CX 5 CE (07491)  
Boehringer Mannheim Hitachi 737  
(07165)  
Boehringer Mannheim Hitachi 747  
(07166)  
Boehringer Mannheim Hitachi 911  
(07377)  
Chiron Diagnostics 550 Express  
(10352)  
Dade Dimension AR (13421)  
Dade Dimension ES (13420)  
Dade Dimension RxL (13436)  
Dade Dimension XL (13422)  
Dade aca Star (13423)  
Du Pont Dimension (13086)  
Du Pont Dimension AR (13087)  
Du Pont Dimension ES (13215)  
Du Pont Dimension XL (13355)  
Olympus AU 5000 (46001)  
Olympus AU 5200 (46143)  
Technicon RA XT (61013)  
ANALYTE: Amikacin (0425)

**TEST SYSTEM, ASSAY,  
EXAMINATION:**

Dade aca Star (13423)  
ANALYTE: Amphetamines (0428)

**TEST SYSTEM, ASSAY,  
EXAMINATION:**

Applied Biotech SureStep Drug  
Screen AMP Test (04674)  
Dade Dimension AR (13421)  
Dade Dimension RxL (13436)  
Dade Dimension XL (13422)  
Dade aca Star (13423)  
Roche OnTrak TESTCUP Collection/  
Urinalysis Panel (55146)  
ANALYTE: Barbiturates (0701)

**TEST SYSTEM, ASSAY,  
EXAMINATION:**

Chiron Diagnostics 550 Express  
(10352)  
Ciba Corning 550 Express (10038)  
Dade Dimension AR (13421)  
Dade Dimension RxL (13436)  
Dade Dimension XL (13422)  
Dade aca Star (13423)  
ANALYTE: Benzodiazepines (0702)

**TEST SYSTEM, ASSAY,  
EXAMINATION:**

Dade Dimension AR (13421)  
Dade Dimension RxL (13436)  
Dade Dimension XL (13422)  
Dade aca Star (13423)  
ANALYTE: Cannabinoids (THC) (1009)

**TEST SYSTEM, ASSAY,  
EXAMINATION:**

Applied Biotech SureStep Drug  
Screen THC Test (04675)  
Dade Dimension AR (13421)  
Dade Dimension RxL (13436)  
Dade Dimension XL (13422)  
Dade aca Star (13423)  
TCPI One-Step Urine DOA  
Cannabinoid (THC) (61258)  
ANALYTE: Carbamazepine (1010)

**TEST SYSTEM, ASSAY,  
EXAMINATION:**

Behring OPUS (07793)  
Behring OPUS Magnum (07794)  
Chiron Diagnostics 550 Express  
(10352)  
Dade Dimension AR (13421)  
Dade Dimension ES (13420)  
Dade Dimension RxL (13436)  
Dade Dimension XL (13422)  
Dade aca Star (13423)  
Du Pont Dimension (13086)  
Du Pont Dimension AR (13087)  
Du Pont Dimension ES (13215)  
Du Pont Dimension XL (13355)  
ANALYTE: Carboxyhemoglobin (1012)

**TEST SYSTEM, ASSAY,  
EXAMINATION:**

A-VOX Systems AVOXimeter 4000  
(04678)  
Chiron Diagnostics 2500 CO-oximeter  
(10346)  
Chiron Diagnostics 270 CO-oximeter  
(10347)  
Chiron Diagnostics 845 (10370)  
Chiron Diagnostics 855 (10372)  
Chiron Diagnostics 865 (10374)  
Instrumentation Laboratory IL  
Synthesis (28466)  
ANALYTE: Cocaine Metabolites (1023)

**TEST SYSTEM, ASSAY,  
EXAMINATION:**

Dade Dimension AR (13421)

Dade Dimension RxL (13436)  
Dade Dimension XL (13422)  
Dade aca Star (13423)  
ANALYTE: Digitoxin (1303)

**TEST SYSTEM, ASSAY,  
EXAMINATION:**

Dade aca Star (13423)  
ANALYTE: Digoxin (1304)

**TEST SYSTEM, ASSAY,  
EXAMINATION:**

Beckman IMAGE Immunochemistry  
System (07816)  
Behring OPUS (07793)  
Chiron Diagnostics 550 Express  
(10352)  
Chiron Diagnostics ACS 180 (10375)  
Chiron Diagnostics ACS 180 Plus  
(10376)  
Ciba Corning ACS 180 Plus (10336)  
Dade Dimension AR (13421)  
Dade Dimension ES (13420)  
Dade Dimension RxL (13436)  
Dade Dimension XL (13422)  
Dade aca Star (DGN A) (13426)  
Dade aca Star (manual pretreatment)  
(13427)  
bioMerieux Vitek VIDAS (07806)  
ANALYTE: Ethanol (Alcohol) (1608)

**TEST SYSTEM, ASSAY,  
EXAMINATION:**

Chiron Diagnostics 550 Express  
(10352)  
Dade Dimension AR (13421)  
Dade Dimension ES (13420)  
Dade Dimension RxL (13436)  
Dade Dimension XL (13422)  
Dade aca Star (13423)  
Technicon AXON (61001)  
ANALYTE: Ethosuximide (1609)

**TEST SYSTEM, ASSAY,  
EXAMINATION:**

Dade aca Star (13423)  
ANALYTE: Gentamicin (2202)

**TEST SYSTEM, ASSAY,  
EXAMINATION:**

Behring OPUS (07793)  
Chiron Diagnostics ACS 180 (10375)  
Chiron Diagnostics ACS 180 Plus  
(10376)  
Ciba Corning ACS 180 Plus (10336)  
Dade Dimension AR (13421)  
Dade Dimension ES (13420)  
Dade Dimension RxL (13436)  
Dade Dimension XL (13422)  
Dade aca Star (13423)  
Du Pont Dimension AR (13087)  
Du Pont Dimension ES (13215)  
Du Pont Dimension XL (13355)  
ANALYTE: Lidocaine (3710)

**TEST SYSTEM, ASSAY,  
EXAMINATION:**

Dade aca Star (13423)  
ANALYTE: Lithium (3712)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

AVL 9180 (04664)  
Chiron Diagnostics 480 (10351)  
Chiron Diagnostics 654 (10367)  
Medica EasyStat Na/K/Li Analyzer  
(40256)  
ANALYTE: Lysergic Acid Diethylamide  
(LSD) (3715)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

Boehringer Mannheim Hitachi 717  
(07163)  
ANALYTE: Methadone (4003)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

Dade Dimension AR (13421)  
Dade Dimension RxL (13436)  
Dade Dimension XL (13422)  
Dade aca Star (13423)  
ANALYTE: Methamphetamines (4004)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

Applied Biotech SureStep Drug  
Screen Methamphetamine Test  
(04669)  
Chiron Diagnostics 550 Express  
(10352)  
ANALYTE: Methotrexate (4006)

*TEST SYSTEM,  
ASSAY, EXAMINATION:*

Dade aca Star (13423)  
ANALYTE: Morphine (4020)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

Applied Biotech SureStep Drug  
Screen MOR Test (04676)  
ANALYTE: N-Acetylprocainamide  
(NAPA) (4301)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

Behring OPUS (07793)  
Behring OPUS Magnum (07794)  
Behring OPUS Plus (07795)  
Chiron Diagnostics 550 Express  
(10352)  
Dade aca Star (13423)  
ANALYTE: Opiates (4601)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

Dade Dimension AR (13421)  
Dade Dimension RxL (13436)  
Dade Dimension XL (13422)  
Dade aca Star (13423)  
ANALYTE: Phencyclidine (PCP) (4901)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

Dade Dimension AR (13421)  
Dade Dimension RxL (13436)  
Dade Dimension XL (13422)  
Dade aca Star (13423)  
ANALYTE: Phenobarbital (4902)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

Behring OPUS (07793)  
Chiron Diagnostics 550 Express  
(10352)  
Dade Dimension AR (13421)  
Dade Dimension ES (13420)  
Dade Dimension RxL (13436)  
Dade Dimension XL (13422)  
Dade aca Star (13423)  
ANALYTE: Phenytoin (4903)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

Behring OPUS (07793)  
Chiron Diagnostics 550 Express  
(10352)  
Dade Dimension AR (13421)  
Dade Dimension ES (13420)  
Dade Dimension RxL (13436)  
Dade Dimension XL (13422)  
Dade aca Star (13423)  
ANALYTE: Primidone (4912)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

Beckman Synchron CX 5 CE (07491)  
Boehringer Mannheim Hitachi 737  
(07165)  
Boehringer Mannheim Hitachi 747  
(07166)  
Boehringer Mannheim Hitachi 911  
(07377)  
Dade aca Star (13423)  
Olympus AU 5000 (46001)  
Olympus AU 5200 (46143)  
ANALYTE: Procainamide (4913)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

Beckman Synchron CX 5 CE (07491)  
Behring OPUS (07793)  
Behring OPUS Magnum (07794)  
Behring OPUS Plus (07795)  
Boehringer Mannheim Hitachi 737  
(07165)  
Boehringer Mannheim Hitachi 747  
(07166)  
Boehringer Mannheim Hitachi 911  
(07377)  
Chiron Diagnostics 550 Express  
(10352)  
Dade aca Star (13423)  
Olympus AU 5000 (46001)  
Olympus AU 5200 (46143)  
Olympus AU 800 (46110)  
Olympus Reply (46089)  
ANALYTE: Quinidine (5202)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

Dade aca Star (13423)  
ANALYTE: Salicylates (5801)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

Chiron Diagnostics 550 Express  
(10352)  
Dade Dimension AR (13421)

Dade Dimension ES (13420)  
Dade Dimension RxL (13436)  
Dade Dimension XL (13422)  
Dade aca Star (13423)  
ANALYTE: Theophylline (6104)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

Behring OPUS (07793)  
Chiron Diagnostics 550 Express  
(10352)  
Chiron Diagnostics ACS 180 (10375)  
Chiron Diagnostics ACS 180 Plus  
(10376)  
Ciba Corning ACS 180 Plus (10336)  
Dade Analyst (13425)  
Dade Dimension AR (13421)  
Dade Dimension ES (13420)  
Dade Dimension RxL (13436)  
Dade Dimension XL (13422)  
Dade aca Star (13423)  
bioMerieux Vitek VIDAS (07806)  
ANALYTE: Tobramycin (6112)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

Behring OPUS (07793)  
Dade Dimension AR (13421)  
Dade Dimension ES (13420)  
Dade Dimension RxL (13436)  
Dade Dimension XL (13422)  
Dade aca Star (13423)  
Du Pont Dimension AR (13087)  
Du Pont Dimension ES (13215)  
Du Pont Dimension XL (13355)  
ANALYTE: Tricyclic Antidepressants  
(6117)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

Beckman Synchron CX 4 (07071)  
Beckman Synchron CX 4 CE (07174)  
Beckman Synchron CX 5 (07072)  
Beckman Synchron CX 5 CE (07491)  
Beckman Synchron CX 7 (07073)  
Boehringer Mannheim Hitachi 717  
(07163)  
Boehringer Mannheim Hitachi 737  
(07165)  
Boehringer Mannheim Hitachi 747  
(07166)  
Boehringer Mannheim Hitachi 911  
(07377)  
Dade aca Star (13423)  
Olympus AU 5000 (46001)  
Olympus AU 5200 (46143)  
Olympus AU 800 (46110)  
Olympus Reply (46089)  
Roche Cobas FARA (55040)  
ANALYTE: Valproic Acid (6701)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

Beckman Synchron CX 4 Delta  
(07762)  
Beckman Synchron CX 5 CE (07491)  
Beckman Synchron CX 5 Delta  
(07763)  
Beckman Synchron CX 7 Delta  
(07764)

Behring OPUS (07793)  
 Boehringer Mannheim Hitachi 737  
 (07165)  
 Boehringer Mannheim Hitachi 747  
 (07166)  
 Dade aca Star (13423)  
 Olympus AU 5000 (46001)  
 Olympus AU 5200 (46143)  
 Olympus AU 800 (46110)  
 Olympus Reply (46089)

ANALYTE: Vancomycin (6703)

*TEST SYSTEM, ASSAY,  
 EXAMINATION:*

Behring OPUS (07793)  
 Behring OPUS Magnum (07794)  
 Behring OPUS Plus (07795)  
 Chiron Diagnostics ACS 180 (10375)  
 Chiron Diagnostics ACS 180 Plus  
 (10376)  
 Ciba Corning ACS 180 Plus (10336)  
 Dade Dimension AR (13421)  
 Dade Dimension ES (13420)  
 Dade Dimension RxL (13436)  
 Dade Dimension XL (13422)  
 Dade aca Star (13423)  
 Du Pont Dimension (13086)  
 Du Pont Dimension AR (13087)  
 Du Pont Dimension ES (13215)  
 Du Pont Dimension XL (13355)

SPECIALITY/SUBSPECIALITY:

Urinalysis  
 ANALYTE: Hemoglobin, Urine (2564)

*TEST SYSTEM, ASSAY,  
 EXAMINATION:*

Boehringer Mannheim Hitachi 717/  
 Chimera UA PERFECT (07780)  
 Boehringer Mannheim Hitachi 747  
 (STC Auto-Lyte) (07767)  
 Roche Cobas Bio (STC Auto-Lyte)  
 (55200)  
 ANALYTE: Leukocyte Esterase, Urinary  
 (3757)

*TEST SYSTEM, ASSAY,  
 EXAMINATION:*

Boehringer Mannheim Hitachi 717/  
 Chimera UA PERFECT (07780)  
 Boehringer Mannheim Hitachi 747  
 (STC Auto-Lyte) (07767)  
 Roche Cobas Bio (STC Auto-Lyte)  
 (55200)

ANALYTE: Total Solids (Specific  
 Gravity) (6125)

*TEST SYSTEM, ASSAY,  
 EXAMINATION:*

Beckman Synchron CX 4 CE/DRI  
 Gravity-Detect (07802)  
 Beckman Synchron CX 4/DRI Gravity-  
 Detect (07801)  
 Beckman Synchron CX 5 CE/DRI  
 Gravity-Detect (07804)  
 Beckman Synchron CX 5/DRI Gravity-  
 Detect (07803)  
 Beckman Synchron CX 7/DRI Gravity-  
 Detect (07805)  
 Boehringer Mannheim Hitachi 704/

DRI Gravity-Detect (07796)  
 Boehringer Mannheim Hitachi 717/  
 Chimera UA PERFECT (07780)  
 Boehringer Mannheim Hitachi 717/  
 DRI Gravity-Detect (07797)  
 Boehringer Mannheim Hitachi 737/  
 DRI Gravity-Detect (07798)  
 Boehringer Mannheim Hitachi 747/  
 DRI Gravity-Detect (07799)  
 Boehringer Mannheim Hitachi 911/  
 DRI Gravity-Detect (07800)  
 Chiron Diagnostics 550 Express/DRI  
 Gravity-Detect (10379)  
 Ciba Corning 550 Express/DRI  
 Gravity-Detect (10335)  
 IRIS/BM 900UDx Urine Pathology  
 System (28453)  
 Instrumentation Laboratory IL  
 Monarch 1000/DRI Grav-Det  
 (28455)  
 Instrumentation Laboratory IL  
 Monarch 2000/DRI Grav-Det  
 (28456)  
 Olympus AU 5000/DRI Gravity-Detect  
 (46218)  
 Olympus AU 5200/DRI Gravity-Detect  
 (46219)  
 Olympus AU 800/DRI Gravity-Detect  
 (46220)  
 Olympus Reply/DRI Gravity-Detect  
 (46221)  
 Roche Cobas FARA/DRI Gravity-  
 Detect (55211)  
 Roche Cobas Mira/DRI Gravity-Detect  
 (55210)

ANALYTE: Urinary Sediment  
 Microscopic Elements (6405)

*TEST SYSTEM, ASSAY,  
 EXAMINATION:*

IRIS/BM 900UDx Urine Pathology  
 System (28453)  
 Sysmex UF-100 (58410)  
 ANALYTE: Urine Qualitative Dipstick  
 Chemistries (6406)

*TEST SYSTEM, ASSAY,  
 EXAMINATION:*

Bayer CLINITEK 50 Urine Chemistry  
 Analyzer (07788)  
 IRIS/BM 900UDx Urine Pathology  
 System (28453)

SPECIALITY/SUBSPECIALITY:

Virology  
 ANALYTE: Rotavirus (5509)

*TEST SYSTEM, ASSAY,  
 EXAMINATION:*

bioMerieux Vitek VIDAS (07806)  
 COMPLEXITY: HIGH  
 SPECIALITY/SUBSPECIALITY:  
 Bacteriology  
 ANALYTE: Aerobic &/or Anaerobic  
 Organisms-unlimited sources (0412)

*TEST SYSTEM, ASSAY,  
 EXAMINATION:*

Becton Dickinson BBL CRYSTAL N/H  
 ID Sys. (inc. culture) (07807)

ANALYTE: Chlamydia (1016)

*TEST SYSTEM, ASSAY,  
 EXAMINATION:*

Vitek Systems VIDAS Chlamydia  
 Blocking Assay (67102)  
 bioMerieux Vitek VIDAS (07806)  
 bioMerieux Vitek VIDAS Chlamydia  
 Blocking Assay (07825)

ANALYTE: Staphylococcus (5807)

*TEST SYSTEM, ASSAY,  
 EXAMINATION:*

Remel Staph Latex Kit (inc. culture)  
 (55215)

SPECIALITY/SUBSPECIALITY:  
 Endocrinology

ANALYTE: 25-Hydroxyvitamin D (25-  
 OH-D) (0110)

*TEST SYSTEM, ASSAY,  
 EXAMINATION:*

Incstar 25-Hydroxyvitamin D 125I  
 RIA Kit (28374)

ANALYTE: Androstenedione (0460)

*TEST SYSTEM, ASSAY,  
 EXAMINATION:*

Diagnostic Systems DSL-10-3800  
 ACTIVE Androstenedione EIA  
 (13429)

ANALYTE: Catecholamines, Plasma  
 (1056)

*TEST SYSTEM, ASSAY,  
 EXAMINATION:*

Bio-Rad CDM System/Bio-Rad HPLC  
 (07792)

ANALYTE: Cortisol, Urine (extraction  
 procedure) (1095)

*TEST SYSTEM, ASSAY,  
 EXAMINATION:*

Chiron Diagnostics ACS 180 (10375)  
 Chiron Diagnostics ACS 180 Plus  
 (10376)

Ciba Corning ACS 180 Plus (10336)  
 bioMerieux Vitek VIDAS (07806)

ANALYTE: Dehydroepiandrosterone  
 Sulfate (DHEA-SO4) (1310)

*TEST SYSTEM, ASSAY,  
 EXAMINATION:*

Diagnostic Systems DSL-C2700  
 DHEA-S-7 RIA (13433)  
 ANALYTE: Estriol-unconjugated (1607)

*TEST SYSTEM, ASSAY,  
 EXAMINATION:*

Diagnostic Systems DSL-10-3700  
 ACTIVE Unconj. Estriol EIA (13434)  
 ANALYTE: Follicle Stimulating  
 Hormone (FSH) (1908)

*TEST SYSTEM, ASSAY,  
 EXAMINATION:*

Diagnostic Systems DSL-4700  
 ACTIVE FSH IRMA (13432)  
 ANALYTE: Gastrin (2205)

**TEST SYSTEM, ASSAY,  
EXAMINATION:**

Biosyn Gastrin EIA (07786)  
ICN Gastrin EIA (28444)  
ANALYTE: HCG, Total, Serum,  
Quantitative (2555)

**TEST SYSTEM, ASSAY,  
EXAMINATION:**

Diagnostic Systems DSL-10-8300  
ACTIVE Intact hCG ELISA (13428)  
ANALYTE: Homovanillic Acid (HVA)  
(2545)

**TEST SYSTEM, ASSAY,  
EXAMINATION:**

Bio-Rad CDM System/Bio-Rad HPLC  
(07792)  
ANALYTE: Insulin (2812)

**TEST SYSTEM, ASSAY,  
EXAMINATION:**

ALPCO Mercodia Insulin Enzyme  
Immunoassay (ELISA) (04679)  
ANALYTE: Insulin-like Growth Factor-  
II (IGF-II) (2834)

**TEST SYSTEM, ASSAY,  
EXAMINATION:**

Diagnostic Systems DSL-9100  
ACTIVE IGF-II IRMA (13431)  
ANALYTE: Metanephrines, Urine  
(4025)

**TEST SYSTEM, ASSAY,  
EXAMINATION:**

Bio-Rad CDM System/Bio-Rad HPLC  
(07792)  
ANALYTE: Thyroxine (T4) (6109)

**TEST SYSTEM, ASSAY,  
EXAMINATION:**

United Biotech UBI MAGIWEL T4  
(Thyroxine) Quantitative (64034)  
ANALYTE: Triiodothyronine (T3)  
(6119)

**TEST SYSTEM, ASSAY,  
EXAMINATION:**

United Biotech UBI MAGIWEL T3  
(Triiodothyronine) Quant. (64035)  
ANALYTE: Vanillylmandelic Acid  
(VMA) (6710)

**TEST SYSTEM, ASSAY,  
EXAMINATION:**

Bio-Rad CDM System/Bio-Rad HPLC  
(07792)  
SPECIALITY/SUBSPECIALITY: General  
Chemistry  
ANALYTE: Alkaline Phosphatase (ALP)  
(0416)

**TEST SYSTEM, ASSAY,  
EXAMINATION:**

HiChem Alkaline Phosphatase  
Reagent Kit (manual) (25262)  
ANALYTE: Alkaline Phosphatase Bone  
Specific (BAP) (0518)

**TEST SYSTEM, ASSAY,  
EXAMINATION:**

Hybritech Tandem-R Ostase (25170)  
ANALYTE: Blood Gases with pH (0708)

**TEST SYSTEM, ASSAY,  
EXAMINATION:**

Chiron Diagnostics 158 (10340)  
Chiron Diagnostics 168 (10341)  
ANALYTE: Creatine Kinase (CK) (1034)

**TEST SYSTEM, ASSAY,  
EXAMINATION:**

HiChem Creatine Kinase Reagent Kit  
(manual) (25263)  
ANALYTE: Glycosylated Hemoglobin  
(Hgb A1C) (2204)

**TEST SYSTEM, ASSAY,  
EXAMINATION:**

Bio-Rad MDMS (07781)  
ANALYTE: HDL Cholesterol (2550)

**TEST SYSTEM, ASSAY,  
EXAMINATION:**

Chiron Diagnostics 550 Express  
(10352)  
Chiron Diagnostics 570 Alliance  
(10359)  
Chiron Diagnostics 580 Alliance  
(10362)

Dade Dimension AR (13421)  
Dade Dimension ES (13420)  
Dade Dimension RxL (13436)  
Dade Dimension XL (13422)  
Dade aca Star (13423)  
ANALYTE: Iron Binding Capacity (post  
saturation/separation) (2815)

**TEST SYSTEM, ASSAY,  
EXAMINATION:**

Chiron Diagnostics 550 Express  
(10352)  
Dade Dimension AR (13421)  
Dade Dimension ES (13420)  
Dade Dimension RxL (13436)  
Dade Dimension XL (13422)  
Dade aca Star (13423)  
ANALYTE: Lipoprotein Fractions (3720)

**TEST SYSTEM, ASSAY,  
EXAMINATION:**

Zaxis LFS Lipogel Assay Kit (79049)  
ANALYTE: Oxalate (4605)

**TEST SYSTEM, ASSAY,  
EXAMINATION:**

Chiron Diagnostics 550 Express  
(10352)  
ANALYTE: Phenylalanine (4942)

**TEST SYSTEM, ASSAY,  
EXAMINATION:**

Shield Diagnostics Quantase  
Phenylalanine (58425)  
ANALYTE: Protein Fractions (4920)

**TEST SYSTEM, ASSAY,  
EXAMINATION:**

Sebia Hydragel 15/30 Protein (E) Kit

(for HYDRASYS) (58393)  
Sebia Hydragel IF//IF Penta (for  
HYDRASYS) (58399)  
Sebia Hydragel IF/Double IF/IF Penta  
(manual) (58398)  
ANALYTE: Retinol binding protein  
(5507)

**TEST SYSTEM, ASSAY,  
EXAMINATION:**

The Binding Site Human Retinol  
Binding Protein 'NL' NANORID  
(61253)

ANALYTE: Triglyceride (6118)

**TEST SYSTEM, ASSAY,  
EXAMINATION:**

Horizon Diagnostics Triglycerides-  
GPO Reagent (manual) (25167)  
ANALYTE: Vitamin B6 (6718)

**TEST SYSTEM, ASSAY,  
EXAMINATION:**

ALPCO Vitamin B6 3H REA (04667)  
SPECIALITY/SUBSPECIALITY: General  
Immunology  
ANALYTE: Anti-Cardiolipin Antibodies  
(0434)

**TEST SYSTEM, ASSAY,  
EXAMINATION:**

ALPCO ORGenTec Anti-Cardiolipin  
(IgA) ELISA (04672)  
ALPCO ORGenTec Anti-Cardiolipin  
(IgG/IgM) ELISA (04668)  
Shield Diagnostics DIASTAT anti-  
Cardiolipin IgG/IgM (qual) (58422)  
Shield Diagnostics DIASTAT anti-  
Cardiolipin IgG/IgM (quant) (58421)  
ANALYTE: Anti-Centromere Antibodies  
(0487)

**TEST SYSTEM, ASSAY,  
EXAMINATION:**

Shield Diagnostics DIASTAT Anti-  
Centromere Kit (qual) (58423)  
Shield Diagnostics DIASTAT Anti-  
Centromere Kit (semi-quant)  
(58312)  
ANALYTE: Anti-DNA Antibodies (0435)

**TEST SYSTEM, ASSAY,  
EXAMINATION:**

TheraTest Laborat EL-ANA/  
6(ssDNA,dsDNA,Sm,RNP/Sm,SS-  
A,SS-B) (61235)  
TheraTest Laboratories EL-ANA  
Profiles (anti-dsDNA) (61243)  
TheraTest Laboratories EL-ANA  
Profiles (anti-ssDNA) (61242)  
TheraTest Laboratories EL-ANA  
Profiles (anti-ssDNA, -dsDNA)  
(61239)  
TheraTest Labs EL-ANA/  
7H(ssDNA,dsDNA,Sm,RNP/  
Sm,SSA,SSB,His) (61236)  
TheraTest Labs EL-ANA/  
7S(ss&dsDNA,Sm,RNP/  
Sm,SSA,SSB,ScI-70) (61237)

TheraTest Labs EL-ANA/  
8(ss&dsDNA,Sm,RNP/  
Sm,SSA,SSB,Scl70,H) (61238)  
ANALYTE: Anti-ENA Antibodies (0507)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

INOVA Diag QUANTALite ENA6  
ELISA/Sm,RNP,SSA,SSB,Scl-70,Jo-  
1 (28465)

Immuno Concepts RELISA Sng Well/  
RNP,Sm,SS-A,SS-B,Scl-70,Jo1  
(28467)

ANALYTE: Anti-Glomerular Basement  
Membrane (GBM) Antibodies (0524)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

Shield Diagnostics DIASTAT anti-  
GBM (qual) (58427)

Shield Diagnostics DIASTAT anti-  
GBM (semi-quant) (58426)

ANALYTE: Anti-Histone Antibodies  
(0437)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

TheraTest Laboratories EL-ANA  
Profiles (anti-Histone) (61249)

TheraTest Labs EL-ANA/  
7H(ssDNA,dsDNA,Sm,RNP/  
Sm,SSA,SSB,His) (61236)

TheraTest Labs EL-ANA/  
8(ss&dsDNA,Sm,RNP/  
Sm,SSA,SSB,Scl70,H) (61238)

ANALYTE: Anti-Jo-1 (0438)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

Immuno Concepts RELISA Jo-1  
(28449)

TheraTest Laboratories EL-ANA  
Profiles (anti-Jo-1) (61250)

ANALYTE: Anti-Mitochondrial  
Antibodies (AMTA) (0439)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

The Binding Site Rat Liver, Kidney,  
Stomach IFA Kit (61254)

ANALYTE: Anti-Myeloperoxidase  
(MPO) Antibodies (0505)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

Wampole MPO IgG,A,M ELISA  
(70191)

ANALYTE: Anti-Neutrophil Cytoplasm  
Antibodies (0440)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

INOVA Diagnostics NOVA Lite ANCA  
(28463)

Scimedx Anti-Neutrophil  
Cytoplasmic Ab (ANCA) (IFA)  
(58419)

ANALYTE: Anti-Nuclear Antibodies  
(ANA) (0441)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

IMI MICRO21/Immuno Concepts  
Colorzyme ANA (28447)

The Binding Site Rat Liver, Kidney,  
Stomach IFA Kit (61254)

ANALYTE: Anti-Parietal Cell  
Antibodies (0442)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

The Binding Site Rat Liver, Kidney,  
Stomach IFA Kit (61254)

ANALYTE: Anti-Proteinase-3 (PR-3)  
Antibodies (0525)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

Shield Diagnostics DIASTAT Anti-  
PR3 (cANCA) (qual) (58424)

Shield Diagnostics DIASTAT Anti-  
PR3 (cANCA) (semi-quant) (58329)

Wampole PR-3 IgG,A,M ELISA  
(70190)

ANALYTE: Anti-RNP  
(Ribonucleoprotein) (0443)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

TheraTest Laboratories EL-ANA  
Profiles (anti-Sm, -RNP) (61240)

ANALYTE: Anti-RNP-Sm Antibodies  
(0502)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

Immuno Concepts RELISA Sm/RNP  
(28451)

TheraTest Laborat EL-ANA/  
6(ssDNA,dsDNA,Sm,RNP/Sm,SS-  
A,SS-B) (61235)

TheraTest Laboratories EL-ANA  
Profiles (anti-RNP/Sm) (61245)

TheraTest Labs EL-ANA/  
7H(ssDNA,dsDNA,Sm,RNP/  
Sm,SSA,SSB,His) (61236)

TheraTest Labs EL-ANA/  
7S(ss&dsDNA,Sm,RNP/  
Sm,SSA,SSB,Scl-70) (61237)

TheraTest Labs EL-ANA/  
8(ss&dsDNA,Sm,RNP/  
Sm,SSA,SSB,Scl70,H) (61238)

ANALYTE: Anti-Ribosomal P  
Antibodies (0445)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

Immuno Probe Ribosomal P EIA Test  
(28441)

ANALYTE: Anti-SS-A/Ro (0446)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

Immuno Concepts RELISA SS-A/  
Ro-SS-B/LA (28450)

TheraTest Laborat EL-ANA/  
6(ssDNA,dsDNA,Sm,RNP/Sm,SS-  
A,SS-B) (61235)

TheraTest Laboratories EL-ANA

Profiles (anti-SS-A) (61246)  
TheraTest Laboratories EL-ANA  
Profiles (anti-SS-A, -SS-B) (61241)

TheraTest Labs EL-ANA/  
7H(ssDNA,dsDNA,Sm,RNP/  
Sm,SSA,SSB,His) (61236)

TheraTest Labs EL-ANA/  
7S(ss&dsDNA,Sm,RNP/  
Sm,SSA,SSB,Scl-70) (61237)

TheraTest Labs EL-ANA/  
8(ss&dsDNA,Sm,RNP/  
Sm,SSA,SSB,Scl70,H) (61238)

ANALYTE: Anti-SS-B/La (0447)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

Immuno Concepts RELISA SS-A/  
Ro-SS-B/LA (28450)

TheraTest Laborat EL-ANA/  
6(ssDNA,dsDNA,Sm,RNP/Sm,SS-  
A,SS-B) (61235)

TheraTest Laboratories EL-ANA  
Profiles (anti-SS-A, -SS-B) (61241)

TheraTest Laboratories EL-ANA  
Profiles (anti-SS-B) (61247)

TheraTest Labs EL-ANA/  
7H(ssDNA,dsDNA,Sm,RNP/  
Sm,SSA,SSB,His) (61236)

TheraTest Labs EL-ANA/  
7S(ss&dsDNA,Sm,RNP/  
Sm,SSA,SSB,Scl-70) (61237)

TheraTest Labs EL-ANA/  
8(ss&dsDNA,Sm,RNP/  
Sm,SSA,SSB,Scl70,H) (61238)

ANALYTE: Anti-Scl-70 (0448)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

Immuno Concepts RELISA Scl-70  
(28452)

TheraTest Laboratories EL-ANA  
Profiles (anti-Scl-70) (61248)

TheraTest Labs EL-ANA/  
7S(ss&dsDNA,Sm,RNP/  
Sm,SSA,SSB,Scl-70) (61237)

TheraTest Labs EL-ANA/  
8(ss&dsDNA,Sm,RNP/  
Sm,SSA,SSB,Scl70,H) (61238)

ANALYTE: Anti-Sm (Smith) (0450)

*TEST SYSTEM, ASSAY,  
EXAMINATION:*

Immuno Concepts RELISA Sm/RNP  
(28451)

TheraTest Laborat EL-ANA/  
6(ssDNA,dsDNA,Sm,RNP/Sm,SS-  
A,SS-B) (61235)

TheraTest Laboratories EL-ANA  
Profiles (anti-Sm) (61244)

TheraTest Laboratories EL-ANA  
Profiles (anti-Sm, -RNP) (61240)

TheraTest Labs EL-ANA/  
7H(ssDNA,dsDNA,Sm,RNP/  
Sm,SSA,SSB,His) (61236)

TheraTest Labs EL-ANA/  
7S(ss&dsDNA,Sm,RNP/  
Sm,SSA,SSB,Scl-70) (61237)

TheraTest Labs EL-ANA/  
8(ss&dsDNA,Sm,RNP/

- Sm.SSA,SSB,ScI70,H) (61238)  
ANALYTE: Anti-Smooth Muscle  
Antibodies (ASMA) (0451)  
*TEST SYSTEM, ASSAY,  
EXAMINATION:*  
The Binding Site Rat Liver, Kidney,  
Stomach IFA Kit (61254)  
ANALYTE: Anti-Thyroglobulin  
Antibodies (0453)  
*TEST SYSTEM, ASSAY,  
EXAMINATION:*  
IMMCO Diagnostics ImmuLisa Anti-  
Thyroglobulin (Tg) Ab ELISA  
(28443)  
ANALYTE: Beta-2 microglobulin (0703)  
*TEST SYSTEM, ASSAY,  
EXAMINATION:*  
Roche Cobas Bio without DENS  
(manual data reduction) (55207)  
ANALYTE: Cytomegalovirus Antibodies  
(1039)  
*TEST SYSTEM, ASSAY,  
EXAMINATION:*  
Incstar CMV IgG "fast" ELISA (28461)  
Incstar CMV IgG ELISA (28460)  
Incstar CMV IgM Capture ELISA  
(28462)  
Quest SeraQuest CMV IgG (manual/  
qual.) (52046)  
Quest SeraQuest CMV IgG/Hyperion  
HyPrep Plus (man. calc.) (52047)  
ANALYTE: Entamoeba histolytica  
Antibodies (1601)  
*TEST SYSTEM, ASSAY,  
EXAMINATION:*  
Trend Scientific TREND Amebiasis  
(E. histolytica) (spectro) (61231)  
Trend Scientific TREND Amebiasis  
(E. histolytica) (visual) (61232)  
ANALYTE: Helicobacter pylori  
Antibodies (2513)  
*TEST SYSTEM, ASSAY,  
EXAMINATION:*  
elias usa Varelisa Helicobacter pyl.  
Abs (IgG) (16112)  
ANALYTE: Herpes simplex I and/or II  
Antibodies (2530)  
*TEST SYSTEM, ASSAY,  
EXAMINATION:*  
Incstar HSV I/II IgG "fast" ELISA  
(28458)  
Incstar HSV I/II IgG ELISA (28459)  
ANALYTE: Lyme Disease Antibodies  
(Borrelia burgdorferi Abs) (3714)  
*TEST SYSTEM, ASSAY,  
EXAMINATION:*  
MarDx Lyme Disease (IgG) Marblot  
Strip Test System (40206)  
MarDx Lyme Disease (IgM) Marblot  
Strip Test System (40210)  
ANALYTE: Mumps Antibodies (4007)  
*TEST SYSTEM, ASSAY,  
EXAMINATION:*  
Zeus Mumps IgG ELISA (79051)  
ANALYTE: Rheumatoid Factor (RF)  
(5508)  
*TEST SYSTEM, ASSAY,  
EXAMINATION:*  
Hemagen Rheumatoid Factor Kit (EIA)  
(25261)  
Zeus Rheumatoid Factor (RF) IgM  
ELISA (79052)  
ANALYTE: Rubella Antibodies (5510)  
*TEST SYSTEM, ASSAY,  
EXAMINATION:*  
Quest SeraQuest Rubella IgG (manual/  
qual.) (52040)  
Quest SeraQuest Rubella IgG (manual/  
semi-quant.) (52041)  
Quest SeraQuest Rubella IgG/  
Hyperion HyPrep Plus (man. calc)  
(52038)  
ANALYTE: Thyroid Peroxidase  
Autoantibodies (TPO) (6135)  
*TEST SYSTEM, ASSAY,  
EXAMINATION:*  
IMMCO Diagnostics ImmuLisa Anti-  
Thyroid Peroxidase (TPO) Ab  
(28442)  
ANALYTE: Toxoplasma gondii  
Antibodies (6113)  
*TEST SYSTEM, ASSAY,  
EXAMINATION:*  
Quest SeraQuest Toxo IgG (manual/  
qual.) (52042)  
Quest SeraQuest Toxo IgG (manual/  
semi-quant.) (52043)  
Quest SeraQuest Toxo IgG/Hyperion  
HyPrep Plus (man. calc.) (52044)  
ANALYTE: Varicella-Zoster Virus  
Antibodies (6704)  
*TEST SYSTEM, ASSAY,  
EXAMINATION:*  
Zeus Varicella-Zoster IgG ELISA  
(79050)  
SPECIALITY/SUBSPECIALITY:  
Hematology  
ANALYTE: Alpha-2-Antiplasmin (0463)  
*TEST SYSTEM, ASSAY,  
EXAMINATION:*  
American Bioproducts STA Compact  
Analyzer (04677)  
Behring Coagulation Timer (BCT)  
(07824)  
Instrumentation Laboratory IL ACL  
6000 (28454)  
ANALYTE: Antithrombin III (ATIII)  
(0456)  
*TEST SYSTEM, ASSAY,  
EXAMINATION:*  
American Bioproducts STA Compact  
Analyzer (04677)  
Behring Coagulation Timer (BCT)  
(07824)  
HemoTec Hepcon/HMS (Platelet  
(07824)  
Instrumentation Laboratory IL ACL  
6000 (28454)  
Sigma Diagnostics Amelung AMAX  
CS-190 (auto dilution) (58413)  
Sigma Diagnostics Amelung AMAX  
CS-190 (manual dilution) (58414)  
ANALYTE: Coagulation Factors (1044)  
*TEST SYSTEM, ASSAY,  
EXAMINATION:*  
American Bioproducts STA Compact  
Analyzer (04677)  
Behring Coagulation Timer (BCT)  
(07824)  
Instrumentation Laboratory IL ACL  
6000 (28454)  
Sigma Diagnostics Amelung AMAX  
CS-190 (auto dilution) (58413)  
Sigma Diagnostics Amelung AMAX  
CS-190 (manual dilution) (58414)  
Sigma Diagnostics Amelung KC 4 A  
Micro Coagulation Analyzer (58412)  
ANALYTE: Fibrinogen (1905)  
*TEST SYSTEM, ASSAY,  
EXAMINATION:*  
Sigma Diagnostics Amelung KC 1 A  
Coagulation Analyzer (58411)  
Sigma Diagnostics Amelung KC 4 A  
Micro Coagulation Analyzer (58412)  
ANALYTE: Heparin (2518)  
*TEST SYSTEM, ASSAY,  
EXAMINATION:*  
American Bioproducts STA Compact  
Analyzer (04677)  
Behring Coagulation Timer (BCT)  
(07824)  
Instrumentation Laboratory IL ACL  
6000 (28454)  
ANALYTE: Heparin, Low Molecular  
Weight (LMWH) (2558)  
*TEST SYSTEM, ASSAY,  
EXAMINATION:*  
American Bioproducts STA Compact  
Analyzer (04677)  
ANALYTE: Plasminogen (4907)  
*TEST SYSTEM, ASSAY,  
EXAMINATION:*  
American Bioproducts STA Compact  
Analyzer (04677)  
Behring Coagulation Timer (BCT)  
(07824)  
Instrumentation Laboratory IL ACL  
6000 (28454)  
ANALYTE: Plasminogen Activator  
Inhibitor (PAI) (4936)  
*TEST SYSTEM, ASSAY,  
EXAMINATION:*  
Biopool TintElize PAI-1 (07787)  
ANALYTE: Platelet Activated Clot Ratio  
(4977)  
*TEST SYSTEM, ASSAY,  
EXAMINATION:*  
HemoTec Hepcon/HMS (Platelet



- Function Test) (25243)  
ANALYTE: Protein C (4929)  
*TEST SYSTEM, ASSAY, EXAMINATION:*  
American Bioproducts STA Compact Analyzer (04677)  
Behring Coagulation Timer (BCT) (07824)  
Instrumentation Laboratory IL ACL 6000 (28454)  
ANALYTE: Protein S (4930)  
*TEST SYSTEM, ASSAY, EXAMINATION:*  
American Bioproducts STA Compact Analyzer (04677)  
Instrumentation Laboratory IL ACL 6000 (28454)  
ANALYTE: White Blood Cell Differential (WBC Diff) (7001)  
*TEST SYSTEM, ASSAY, EXAMINATION:*  
IMI MICRO21 (with intrpret. atypical/immature cells) (28445)  
SPECIALITY/SUBSPECIALITY: Mycobacteriology  
ANALYTE: Mycobacteria (4024)  
*TEST SYSTEM, ASSAY, EXAMINATION:*  
Becton Dickinson BBL MGIT/ Mycobacteria Growth Indicator (07808)  
Organon Teknika MB/BacT Microbial Detection System (46215)  
ANALYTE: Mycobacterium avium complex (4009)  
*TEST SYSTEM, ASSAY, EXAMINATION:*  
Remel MycoAKT Culture ID M. avium complex (inc. cult.) (55217)  
ANALYTE: Mycobacterium kansasii (4014)  
*TEST SYSTEM, ASSAY, EXAMINATION:*  
Remel MycoAKT Culture ID M. kansasii (inc. cult.) (55218)  
ANALYTE: Mycobacterium tuberculosis complex (4015)  
*TEST SYSTEM, ASSAY, EXAMINATION:*  
Remel MycoAKT Culture ID M. tuberculosis cplx (inc. cult.) (55216)  
SPECIALITY/SUBSPECIALITY: Parasitology  
ANALYTE: Cryptosporidium (1109)  
*TEST SYSTEM, ASSAY, EXAMINATION:*  
TechLab Crypto-Cel IF Test (61262)  
TechLab Crypto/Giardia-Cel IF Test (61263)  
Trend Scientific Crypto. parvum Dir Detect System (Spectro) (61252)
- Trend Scientific Crypto. parvum Dir Detect System (Visual) (61251)  
ANALYTE: Entamoeba histolytica (1631)  
*TEST SYSTEM, ASSAY, EXAMINATION:*  
TechLab E. histolytica Test (ELISA) (spectro) (61261)  
TechLab E. histolytica Test (ELISA) (visual) (61260)  
ANALYTE: Giardia lamblia (2222)  
*TEST SYSTEM, ASSAY, EXAMINATION:*  
TechLab Crypto/Giardia-Cel IF Test (61263)  
SPECIALITY/SUBSPECIALITY: Toxicology / TDM  
ANALYTE: Benzodiazepines (0702)  
*TEST SYSTEM, ASSAY, EXAMINATION:*  
Bio-Rad CDM System/Bio-Rad HPLC (07792)  
ANALYTE: Tricyclic Antidepressants (6117)  
*TEST SYSTEM, ASSAY, EXAMINATION:*  
Bio-Rad CDM System/Bio-Rad HPLC (07792)  
SPECIALITY/SUBSPECIALITY: Virology  
ANALYTE: Cytomegalovirus (1038)  
*TEST SYSTEM, ASSAY, EXAMINATION:*  
Du Pont Alliance CMV-Direct EA IFA (including cell culture) (13386)  
Light Diag. CMV Direct IFA (including cell culture) (37100)  
ANALYTE: Herpes simplex (2529)  
*TEST SYSTEM, ASSAY, EXAMINATION:*  
Diagnostic Hybrids ELVIS HSV GOLD (inc. cell culture) (13435)  
ANALYTE: Influenza A (2828)  
*TEST SYSTEM, ASSAY, EXAMINATION:*  
ZymeTx ViraZyme Culture Confirm. Screen (inc. cell culture) (79047)  
ANALYTE: Influenza B (2829)  
*TEST SYSTEM, ASSAY, EXAMINATION:*  
ZymeTx ViraZyme Culture Confirm. Screen (inc. cell culture) (79047)  
ANALYTE: Parainfluenza 1 (4959)  
*TEST SYSTEM, ASSAY, EXAMINATION:*  
ZymeTx ViraZyme Culture Confirm. Screen (inc. cell culture) (79047)  
ANALYTE: Parainfluenza 2 (4960)  
*TEST SYSTEM, ASSAY, EXAMINATION:*  
ZymeTx ViraZyme Culture Confirm.
- Screen (inc. cell culture) (79047)  
ANALYTE: Parainfluenza 3 (4961)  
*TEST SYSTEM, ASSAY, EXAMINATION:*  
ZymeTx ViraZyme Culture Confirm. Screen (inc. cell culture) (79047)  
ANALYTE: Parainfluenza 4 (4975)  
*TEST SYSTEM, ASSAY, EXAMINATION:*  
ZymeTx ViraZyme Culture Confirm. Screen (inc. cell culture) (79047)  
ANALYTE: Respiratory syncytial virus (5503)  
*TEST SYSTEM, ASSAY, EXAMINATION:*  
bioMerieux Vitek VIDAS (07806)  
COMPLEXITY: WAIVED  
SPECIALITY/SUBSPECIALITY: Endocrinology  
ANALYTE: Ovulation Test (LH) by Visual Color Comparison (9461)  
*TEST SYSTEM, ASSAY, EXAMINATION:*  
Vanguard Biomedical MiniClinic Ovulation Predictor (67100)  
ANALYTE: Urine HCG by Visual Color Comparison Tests (9642)  
*TEST SYSTEM, ASSAY, EXAMINATION:*  
Bionike A/Q Pregnancy Test (07779)  
Chembio Sure Check Pregnancy Test (10334)  
CliniCare CliniStrip Urine Only Pregnancy (10383)  
CliniCare CliniStrip hCG Combo (10384)  
CliniCare CliniStrip hCG Pregnancy (10382)  
Genzyme Contrast Strip hCG (22185)  
Orion Diagnostica UniStep hCG II (46224)  
Vanguard Biomedical MiniStick Pregnancy Test (67101)  
SPECIALITY/SUBSPECIALITY: General Chemistry  
ANALYTE: Glucose Monitoring Devices (FDA Cleared/Home Use) (9221)  
*TEST SYSTEM, ASSAY, EXAMINATION:*  
Boehringer Mannheim Accu-Chek Instant (07789)  
Boehringer Mannheim Accu-Chek Instant DM (07783)  
Boehringer Mannheim Accu-Chek InstantPlus (07782)  
Chematics CHEMCARD Glucose Test (10266)  
LXN Blood Glucose Testing System (37107)  
MediSense ExacTech RSG Blood Glucose System (40257)  
SPECIALITY/SUBSPECIALITY: General Immunology

ANALYTE: Helicobacter pylori Antibodies (2513)  
**TEST SYSTEM, ASSAY, EXAMINATION:**  
 Quidel QuickVue One-Step H. pylori Test for Whole Blood (52037)  
**SPECIALITY/SUBSPECIALITY:**  
 Urinalysis  
 ANALYTE: Urine Dipstick or Tablet Analytes, nonautomated (9641)  
**TEST SYSTEM, ASSAY, EXAMINATION:**  
 Bayer CHEK-STIX U.T.I. Test Strips (07790)  
 Genesis Labs DIA SCREEN 10 Way Reagent Strips: Urinalysis (22182)  
 TCPI URI-TEST Glucose in Urine (61256)  
 TCPI URI-TEST Nitrite in Urine

(61257)  
 [FR Doc. 97-9350 Filed 4-10-97; 8:45 am]  
 BILLING CODE 4163-18-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Proposed Information Collection Activity; Comment Request**

**Proposed Projects**

*Title:* Procedures for Requests To Use Child Care and Development Fund for Construction or Major Renovation of Child Care Facilities.

*OMB No:* New Collection.

*Description:* The Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (Public Law 104-193) allows tribal grantees to use Child Care and Development Fund (CCDF) grant awards for construction and renovation of child care facilities. A tribal grantee must first request and receive approval from the Administration for Children and Families (ACF) before using CCDF funds for construction or major renovation. This information collection contains the statutorily-mandated uniform procedures for the solicitation and consideration of requests. Respondents will be CCDF tribal grantees requesting to use the CCDF funds for construction or major renovation.

*Respondents:* Tribal Governments.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Construction and renovation collection .....	100	1	20	2,000

Estimated Total Annual Burden Hours: 2,000.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the administration for Children and Families, Office of Information Services, Division of Information Resource Management Services, 370 L'Enfant Promenade, S.W., Washington, D.C. 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to

comments and suggestions submitted within 60 days of this publication.

Dated: April 7, 1997.

**Bob Sargis,**

*Acting Reports Clearance Officer.*

[FR Doc. 97-9396 Filed 4-10-97; 8:45 am]

BILLING CODE 4184-01-M

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food And Drug Administration**

[Docket No. 97M-0136]

**Thoratec Laboratories Corp.; Premarket Approval of Thoratec® Ventricular Assist Device System**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice

**SUMMARY:** The Food and Drug Administration (FDA) is announcing its approval of the application by Thoratec Laboratories Corp., Berkeley, CA, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of Thoratec® Ventricular Assist Device System. After reviewing the recommendation of the Circulatory Systems Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of December 20, 1995, of the approval of the application.

**DATES:** Petitions for administrative review by May 12, 1997.

**ADDRESSES:** Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review, to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Dina A. Justice, Center for Devices and Radiological Health (HFZ-450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-443-8262.

**SUPPLEMENTARY INFORMATION:** On June 26, 1992, Thoratec Laboratories Corp., Berkeley, CA 94710, submitted to CDRH an application for premarket approval of Thoratec® Ventricular Assist Device System. The device is a ventricular assist device and is intended as a bridge to cardiac transplantation for use in patients suffering from end-stage heart failure. The patient should meet all of the following criteria: (1) Candidate for cardiac transplantation, (2) imminent risk of dying before donor heart procurement, and (3) dependence on, or incomplete response to, continued vasopressor support.

On December 5, 1994, the Circulatory System Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended approval of the