Once a year the Centers for Medicare and Medicaid Services makes available to physicians and to the general public specific information (including information provided to CMS by the Office of the Inspector General) that is useful in evaluating the performance of laboratories. The Clinical Laboratory Improvement Amendments of 1988 (CLIA) and implementing regulations at 42 CFR 493.1850 require that this listing include the following:

(1) A list of laboratories that have been convicted, under Federal or State laws relating to fraud and abuse, false billing, or kickbacks.

(2) A list of laboratories that have had their CLIA certificates suspended, limited, or revoked, and the reasons for the adverse actions.

(3) A list of persons who have been convicted of violating CLIA requirements, as specified in section 353(1) of the PHS Act, together with circumstances of each case and the penalties imposed.

(4) A list of laboratories on which alternative sanctions have been imposed, showing--
   (i) the effective date of the sanctions;
   (ii) the reason for imposing them;
   (iii) any corrective action taken by the laboratory;
   (iv) if the laboratory has achieved compliance, the verified date of compliance.

(5) A list of laboratories whose accreditation has been withdrawn or revoked and the reasons for the withdrawal or revocation.

(6) All appeals and hearing decisions.

(7) A list of laboratories against which CMS has brought suit under Section 493.1846 and the reasons for those actions.

(8) A list of laboratories that have been excluded from participation in Medicare or Medicaid and the reasons for exclusion.

Civil settlements reached with clinical laboratories are also noted.

The Laboratory Registry is compiled for the calendar year preceding the date the information is made available and also contains corrections of any erroneous statements of information that appeared in the previous registry. A final section includes other specific information that may be useful in evaluating the performance of laboratories, as specified in 42 CFR 493.1850(a). It also includes information provided by CLIA exempt states.
1. LABORATORIES SUBJECT TO CLIA THAT HAVE BEEN CONVICTED, UNDER FEDERAL OR STATE LAWS RELATING TO FRAUD AND ABUSE, FALSE BILLING, OR KICKBACKS.

Stephen Bickel, Director
Stat Medical Laboratories
636 West Imboden Drive
Decatur, Illinois  62521
CLIA ID# 14D0897623

REASON: Owner of Stat Medical Laboratories Stephen Bickel pled guilty to 2 counts of mail fraud in October 2003 and was sentenced for false billing Medicare and Medicaid while using his CLIA certificate. He was sentenced to 60 months in prison and order to pay restitution in the amount of $2,521,577.42. Plea agreement and judgment filed on August 18, 2004.

The following was supplied by the Office of the Inspector General.

Abe Oyamada, Director
SGV Laboratory Inc.
221NSan Dimas Ave Suite B
San Dimas, California  91773
CLIA ID# 05D0719679

Sol Teitelbaum, Director
Medical Diagnostic Laboratories Inc.
10136 Artisia Place
Bellflower, California  90706
CLIA ID# 05D0913435

Harry Bauer, Director
1111 W. 6th Street #B1
Los Angeles, California  90017
CLIA ID# 05D0913912

Abe Oyamada, Director
California Lab Access Inc.
2007 Wilshire Blvd., #303
Los Angeles, California  90057
CLIA ID# 05D0943447
2. LABORATORIES THAT HAVE HAD THEIR CLIA CERTIFICATE SUSPENDED, LIMITED, OR REVOKED, AND THE REASON FOR THE ADVERSE ACTION.
(Medicare cancellation, a principal sanction, has been included in this category.)

Robert Rook, M.D., Director
Conway Family Practice
919 Locust
Conway, Arkansas 72034
CLIA ID# 04D0713096

SANCTION: Cancellation of approval to receive Medicare payment for all laboratory services and revocation of CLIA certificate.

EFFECTIVE DATE: January 5, 2004 (Medicare cancellation)
February 18, 2004 (Revocation)

REASON: Failure to submit an acceptable plan of correction. Condition level non-compliance.

Patricia G. McGarry, M.D., Director
Salem Family Practice Clinic, PA
6640 Congo Road
Benton, Arkansas 72015
CLIA ID# 04D0936265

SANCTION: Cancellation of approval to receive Medicare payment for all laboratory services. Pending revocation of the CLIA certificate based on Appeal.

EFFECTIVE DATE: November 8, 2004 (Medicare cancellation)
December 22, 2004 (Revocation)

REASON: Condition level non-compliance; on-site monitoring. Failure to provide an acceptable Plan of Correction.

Walter Schreiber, M.D., Director
12095 West Washington Blvd.
Los Angeles, California 90066-5826
CLIA ID# 05D0545697

SANCTION: Cancellation of approval to receive Medicare payment for all laboratory services and revocation of CLIA certificate.

EFFECTIVE DATE: March 20, 2004 (Medicare cancellation)
May 4, 2004 (Revocation)

REASON: Condition level non-compliance.
Shanti Miglani Sahagal, M.D., Director
United Medical Reference Laboratory
4125 Verdugo Road
Los Angeles, California 90065
**CLIA ID# 05D0551448**

**SANCTION:** Cancellation of approval to receive Medicare payment for all laboratory services and revocation of CLIA certificate.

**EFFECTIVE DATE:** October 26, 2004 (Medicare cancellation)

**REASON:** Condition level non-compliance.

**STATUS:** Revocation pending appeal.

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Jack Wasserman, M.D., Director
Scripps Ranch Medical Clinic
9999 Mira Mesa Blvd., #103
San Diego, California 92131
**CLIA ID# 05D0571145**

**SANCTION:** Revocation of CLIA certificate.

**EFFECTIVE DATE:** April 21, 2004

**REASON:** Improper proficiency testing referral and Condition level non-compliance.

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Dom T. Salamanca, CLB, Director
Millennium Clinical Laboratories, Inc.
401 South Flower Street
Burbank, California 91502
**CLIA ID# 05D0672667**

**SANCTION:** Revocation of CLIA certificate.

**EFFECTIVE DATE:** September 13, 2004

**REASON:** Condition level non-compliance causing immediate and serious threat to the health and safety of patients.
Sukoo J. Whang, M.D., Director  
Dimensions Medical Laboratories, Inc.  
18250 Roscoe Boulevard, Suite 120 
Northridge, California 91325  
**CLIA ID# 05D0724776**

**SANCTION:** Cancellation of approval to receive Medicare payment for all laboratory services, suspension and revocation of CLIA certificate.

**EFFECTIVE DATE:** October 17, 2004 (Medicare cancellation)  
October 20, 2004 (CLIA suspension)

**REASON:** Condition level non-compliance causing immediate and serious threat to the health and safety of patients.

**STATUS:** Revocation pending hearing.

Norvelle Harris, M.D., Director  
Bethesda Pathology Clinical, Inc.  
4520 Wilshire Blvd. Suite 104 
Los Angeles, California 90010 
**CLIA ID# 05D0869567**

**SANCTION:** Revocation of CLIA certificate.

**EFFECTIVE DATE:** February 3, 2004

**REASON:** CLIA regulation prohibit the owner, operator or director of a laboratory whose CLIA certificate has been revoked from owning, operating or directing any clinical laboratory for a period of two years from the date of revocation.

Luis Hernandez, M.D., Director  
American Diagnostic Labs  
9209 South Colima Road, Suite 2300 
Whittier, California 90605  
**CLIA ID# 05D0954736**

**SANCTION:** Revocation of CLIA certificate.

**EFFECTIVE DATE:** June 9, 2004

**REASON:** Condition level non-compliance causing immediate and serious threat to the health and safety of patients.
Issac Melamed, M.D, Director  
Child First Pediatrics  
7336 S Yosemite #200  
Englewood, Colorado 80112  
**CLIA ID# 06D0511723**

**SANCTION:** Limitation of CLIA certificate and limitation of approval receive Medicare/Medicaid payment for the specialty Hematology.

**EFFECTIVE DATE:** March 22, 2004

**REASON:** Condition level non-compliance.

Ashok Khanna, M.D., Director  
Florida Primary Care Center  
2918 N. Pine Hills Road  
Orlando, Florida 32808  
**CLIA ID# 10D0275247**

**SANCTION:** Cancellation of approval to receive Medicare payment for all laboratory services and revocation of CLIA certificate.

**EFFECTIVE DATE:** March 29, 2004

**REASON:** Failure to correct deficiencies. Failure to submit an acceptable allegation of compliance.

Lee Woodall, M.D., Director  
101 Houston Street  
Barnesville, Georgia 30204  
**CLIA ID# 11D0257012**

**SANCTION:** Suspension of approval to receive Medicare payment and limitation of certificate for the analyte, (White Blood Cell).

**EFFECTIVE DATE:** July 2, 2004

**REASON:** Condition level non-compliance; failure to successfully perform proficiency testing.
Gilbert Harris, M.D., Director  
Athens Associates Family Practice  
300 Hawthorne Lane  
Athens, Georgia 30306  
**CLIA ID# 11D0261921**

- **SANCTION:** Suspension of approval to receive Medicare payment and limitation of certificate for the analyte (Hemoglobin).
- **EFFECTIVE DATE:** April 17, 2004
- **REASON:** Condition level non-compliance; failure to successfully perform proficiency testing.
- **STATUS:** Reinstated July 14, 2004

Marilyn Carter, M.D., Director  
Augusta Assoc of International Medicine and Rheumatolgy  
2361 Tobacco Road  
Augusta, Georgia 30906  
**CLIA ID# 11D0886932**

- **SANCTION:** Suspension of approval to receive Medicare payment and limitation of certificate (Microbiology).
- **EFFECTIVE DATE:** April 17, 2004
- **REASON:** Condition level non-compliance; failure to successfully perform proficiency testing.

Lee Rippy  M.D., Director  
Newton Women’s Health Center  
7129 Floyd Street  
Covington, Georgia 30014  
**CLIA ID# 11D0888316**

- **SANCTION:** Suspension of approval to receive Medicare payment and limitation of certificate (Microbiology).
- **EFFECTIVE DATE:** April 17, 2004
- **REASON:** Condition level non-compliance; failure to successfully perform proficiency testing.
- **STATUS:** Reinstated July 14, 2004
SANCTION: Suspension of approval to receive Medicare payment and limitation of certificate for the analyte, automated white blood cell differential.

EFFECTIVE DATE: April 9, 2004

REASON: Condition level non-compliance; failure to successfully perform proficiency testing.

SANCTION: Cancellation of approval to receive Medicare payment for all services; suspension and revocation of the CLIA certificate.

EFFECTIVE DATE: January 26, 2004

REASON: Failure to provide plan of correction for standard-level deficiencies.


SANCTION: Cancellation of approval receive Medicare payment for all laboratory services and suspension of CLIA certificate.

EFFECTIVE DATE: June 28, 2004

REASON: Condition level non-compliance resulting in immediate jeopardy to the health of patients.
Jesus Socrates, M.D., Director  
Reference Pathology Services of Maryland  
9411 Philadelphia Road Suite J & K  
Baltimore, Maryland  21237  
**CLIA ID# 21D0932741** 

**SANCTION:** Cancellation of approval to receive Medicare payment for all laboratory services and suspension of CLIA certificate.  

**EFFECTIVE DATE:** September 18, 2004  

**REASON:** Condition level non-compliance resulting immediate jeopardy to the health of patients. 

Bruce Britton, Director  
St Luke Community Hospital  
107 6th Avenue SW  
Ronan, Montana  59864  
**CLIA ID# 27D0411099** 

**SANCTION:** Limitation of CLIA certificate and limitation of approval to receive Medicare/Medicaid payment for the analyte Digoxin. 

**EFFECTIVE DATE:** March 5, 2004  

**REASON:** Condition level non-compliance. 

**STATUS:** Reinstated September 5, 2004. 

Trudi Muir, Director  
Helena Medical Laboratory Inc.  
27 Neill Avenue Suite 103  
Helena, Montana  59601  
**CLIA ID# 27D0667170** 

**SANCTION:** Limitation of CLIA certificate and limitation of approval to receive Medicare/Medicaid payment for the analyte Uric Acid. 

**EFFECTIVE DATE:** March 5, 2004  

**REASON:** Condition level non-compliance. 

**STATUS:** Reinstated June 17, 2004
Gerald Yudell, Director
904 Gramatan Avenue
Mount Vernon, New York 10552
CLIA ID# 33D0138564

SANCTION: Suspension and revocation of CLIA certificate; cancellation of all Medicare/Medicaid payment.

EFFECTIVE DATE: June 17, 2004

REASON: Condition level non-compliance resulting in immediate jeopardy to the health and safety of patient.

STATUS: Certificate revoked; laboratory closed.

Richard N. Stellar, M.D., Director
Long Island Gastroenterology Group
131 West Merrick Road
Merrick, New York 11566
CLIA ID# 33D0154446

SANCTION: Suspension of CLIA certificate and payment for all laboratory services.

EFFECTIVE DATE: July 9, 2004

REASON: Condition level non-compliance; failure to submit an acceptable plan of correction.


Michael Dannenberg, M.D., Director
Dermatology Associates of Huntington
177 Main Street
Huntington, New York 11743
CLIA ID# 33D0157314

SANCTION: Revocation of CLIA certificate and suspension of approval to receive Medicare payment for all laboratory services.

EFFECTIVE DATE: April 20, 2004

REASON: Failure to submit an acceptable Plan of Correction.

STATUS: Certificate revoked.
John J. O’Donnell, M.D., Director  
Smithtown Manor Pediatrics 
317 Middle Country Road 
Smithtown, New York   11787-2818  
**CLIA ID# 33D0159144**

**SANCTION:** Revocation of CLIA certificate and approval to receive Medicare payment Medicare payment for all laboratory services.  

**EFFECTIVE DATE:** September 21, 2004  

**REASON:** Failure to submit acceptable Plan of Correction.  

**STATUS:** Certificate revoked.  

Henry Chinonuma, M.D., Director  
7711 Oswego Road 
Liverpool, New York   13090  
**CLIA ID# 33D0698093**

**SANCTION:** Suspension of CLIA certificate and suspension of approval to receive Medicare payment for all laboratory services.  

**EFFECTIVE DATE:** March 27, 2004  

**REASON:** Condition level non-compliance; failure to submit acceptable Plan of Correction.  

Judith Jakus-Capla, M.D., Director  
530 First Avenue 
New York, New York   10016  
**CLIA ID# 33D0864181**

**SANCTION:** Suspension of CLIA certificate and suspension of approval to receive Medicare payment for all laboratory services.  

**EFFECTIVE DATE:** October 22, 2004  

**REASON:** Condition level non-compliance; failure to submit an acceptable Plan of Correction.  

**STATUS:** Certificate revoked.
Charles E. Womack, M.D., Director  
5252 N. Meridian, Suite 101  
Oklahoma City, Oklahoma 73112  
CLIA ID# 37D0471513

SANCTION: Cancellation of approval to receive Medicare payment for all laboratory services; cancellation and revocation of CLIA certificate.

EFFECTIVE DATE: December 26, 2004 (Medicare/cancellation-CLIA/revocation)

REASON: Failure of laboratory to submit compliance fees.

Malcolm E. Bridwell, M.D., Director  
Village Medical Clinic Inc.  
700 North Hill  
Hobart, Oklahoma 73651  
CLIA ID# 37D0472446

SANCTION: Cancellation of approval to receive Medicare payment for all laboratory services and suspension of CLIA certificate.

EFFECTIVE DATE: July 27, 2004 (Medicare/cancellation-CLIA/suspension)

REASON: Condition level non-compliance; immediate jeopardy, laboratory failed to submit an acceptable plan of correction.


Eddie Stewart, Director  
Stewart Medical Clinic  
327 Chickasha Ave Suite #4  
Chickasha, Oklahoma 73018-2673  
CLIA ID# 37D0889425

SANCTION: Cancellation of approval to receive Medicare payment for all laboratory services suspension and revocation of CLIA certificate.

EFFECTIVE DATE: July 14, 2004 (Medicare/cancellation-CLIA/suspension)

REASON: Failure to submit acceptable Plan of Correction.

Pravin Gadani, M.D., Director
Gadani Associates
30 East Shady Lane
Enola, Pennsylvania 17025
CLIA ID# 39D0185771

SANCTION: Cancellation of approval to receive Medicare payment for all laboratory services and suspension of CLIA certificate.

EFFECTIVE DATE: July 27, 2004

REASON: Condition level non-compliance resulting in immediate jeopardy to the health and safety of patients.

Ada E. Quinones, Director
Laboratorio Clinico Campo Rico
929 Country Club Avenue
San Juan, Puerto Rico 00924
CLIA ID# 40D0693615

SANCTION: Revocation of CLIA certificate and suspension of approval to receive Medicare payment in Immunohematology. Civil money penalty of $10,000.

EFFECTIVE DATE: December 29, 2004

REASON: Improper proficiency testing activities.

STATUS: Hearing requested.

Carmen I. Ocasio, Director
Education Medical Group
P.O. Box 98
Caguas, Puerto Rico 00659
CLIA ID# 40D0961191

SANCTION: Revocation of CLIA certificate and cancellation of approval to receive Medicare payment for all laboratory services.

EFFECTIVE DATE: September 27, 2004

REASON: No Plan of Correction submitted.

STATUS: Certificate revoked.
Sanction: Revocation of CLIA certificate and cancellation of approval to receive Medicare payment for all laboratory services.

Effective Date: September 27, 2004

Reason: No Plan of Correction submitted.

Status: Certificate revoked.

Maria Del Carmen Aguilar, M.D., Director
Clinic Santa Teresa
2136 Yale, Suite A
Houston, Texas  77008
CLIA ID# 45D0959691

Sanction: Cancellation of approval to receive Medicare payment for all laboratory services, cancellation and revocation of CLIA certificate.

Effective Date: May 21, 2004 (Medicare/cancellation)
                  July 10, 2004 (CLIA revocation)

Reason: Failure to submit compliance fees.

Stephen D. Wood, M.D., Director
Foothill Family Clinic
2295 Foothill Drive
Salt Lake City, Utah  84109-3957
CLIA ID# 46D0524018

Sanction: Cancellation of approval to receive Medicare payment for all services and revocation of CLIA certificate.

Effective Date: March 15, 2004 (Medicare cancellation)

Reason: Improper proficiency testing referral.

Status: Revocation pending hearing.
Stephen D. Wood, M.D., Director
Foothill Family Clinic - South
6360 S 3000 E Suite 100
Salt Lake City, Utah  84121

**CLIA ID# 46D0935188**

**SANCTION:** Cancellation of approval to receive Medicare payment for all laboratory services, suspension and revocation of CLIA certificate.

**EFFECTIVE DATE:** March 15, 2004 (Medicare Cancellation)

**REASON:** Improper proficiency testing referral.

**STATUS:** Revocation pending appeal.

G.Q. Khokar, M.D., Director
1322 Stadium Drive
Bluefield, West Virginia  24701

**CLIA ID# 51D0881983**

**SANCTION:** Cancellation of approval to receive Medicare payment for all laboratory services and suspension of CLIA certificate.

**EFFECTIVE DATE:** April 3, 2004

**REASON:** Condition level non-compliance resulting in immediate jeopardy to the health and safety of patients.

**STATUS:** Compliance confirmed May 27, 2004.
3. A LIST OF PERSONS CONVICTED OF VIOLATING CLIA REQUIREMENTS AS SPECIFIED IN SECTION 353(1) OF THE PUBLIC HEALTH SERVICES ACT, WITH THE CIRCUMSTANCES OF EACH CASE AND THE PENALTIES IMPOSED:

NONE
4. A LIST OF LABORATORIES ON WHICH ALTERNATIVE SANCTIONS HAVE BEEN IMPOSED, SHOWING—

   (i) The effective date of the sanctions;
   (ii) The reason for imposing them;
   (iii) Any corrective action taken by the laboratory; and
   (iv) If laboratory has achieved compliance, the verified date of the compliance.

Sybil Hart, M.D., Director
Millard-Henry Clinic of Russellville
111 East Main
Atkins, Arkansas  72823
CLIA ID# 04D0469021

SANCTION: Directed Plan of Correction.

EFFECTIVE DATE: August 10, 2004

REASON: Condition level non-compliance - immediate jeopardy.


Benny Green, M.D., Director
14309 Cantrell Road Suite 7
Little Rock, Arkansas  72223
CLIA ID# 04D0716907

SANCTION: Directed Plan of Correction.

EFFECTIVE DATE: August 10, 2004

REASON: Condition level non-compliance – immediate jeopardy.


Patricia G. McGarry, M.D., Director
Salem Family Practice Clinic
6640 Congo Road
Benton, Arkansas  72015
CLIA ID# 04D0936265

SANCTION: Directed Plan of Correction, State On-Site Monitoring.

EFFECTIVE DATE: November 8, 2004

REASON: Condition level non-compliance.

SANCTION: Directed Plan of Correction.

EFFECTIVE DATE: October 18, 2004

REASON: Condition level non-compliance - immediate jeopardy.

Community Hospital of Huntington Park
Clinical Laboratory
2623 East Slauson Avenue
Huntington Park, California 90255
CLIA ID# 05D0548135 (CAP)

SANCTION: Accreditation with Conditions.

EFFECTIVE DATE: December 28, 2004

REASON: Accredited with the condition of a non-routine inspection to be conducted in March 2005 due to the recurrent deficiencies identified at the October 20, 2004 routine inspection of corrective actions.

STATUS: The laboratory implemented corrective action for all deficiencies. The laboratory is currently accredited.

Shanti Miglani Sahgal, M.D., Director
United Medical Reference Laboratory
4125 Verdugo Road
Los Angeles, California 90065
CLIA ID# 05D0551448

SANCTION: Civil Money Penalty of $3,000 and Portion of a Plan of Correction.

EFFECTIVE DATE: October 26, 2004

REASON: Condition level non-compliance.

STATUS: Revocation pending appeal.
IGO Medical Group Laboratory
9339 Genesee Ave Ste 220
San Diego, California 92121-2196
CLIA ID# 05D0683043 (CAP)

SANCTION: Accreditation with Conditions.

EFFECTIVE DATE: December 13, 2004

REASON: Accredited with the condition of a non-routine inspection to be conducted in March 2005 due to the lack of medical director involvement identified at the September 24, 2004 non-routine inspection. The non-routine inspection will confirm sustained implementation of corrective actions.

STATUS: The laboratory implemented corrective action for all deficiencies. The laboratory is currently accredited.

Sukoo J. Whang, M.D., Director
Dimensions Medical Laboratories, Inc.
18250 Roscoe Blvd. Suite 120
Northridge, California 91325
CLIA ID# 05D0724776

SANCTION: Civil Money Penalty of $3,000 per day and Directed Portion of Correction.

EFFECTIVE DATE: October 17, 2004

REASON: Condition level non-compliance causing immediate and serious threat to the health and safety of patients.

STATUS: Revocation pending appeal.

Hal Ridgeway M.D., Director
Forest Hill Dermatology Associates
3400 Forest Hill Blvd.
West Palm beach, Florida 33406
CLIA ID# 10D0687272

SANCTION: Civil Money Penalty of $6,500 per day and Directed Plan of Correction.

EFFECTIVE DATE: September 23, 2004

REASON: Condition level non-compliance; testing outside of CLIA certificate.
SANCTION: Probation of Accreditation.

EFFECTIVE DATE: October 20, 2004

REASON: Probation of the laboratory’s accreditation due to significant number and severity of deficiencies identified during complaint inspection on September 30 and October 1, 2004.

STATUS: Laboratory corrected deficiencies; correction confirmed during non-routine inspection January 12, 2005, and probation was lifted on January 25, 2005. The laboratory is currently accredited.

Michael B. Pearlman, M.D., Director
5400 Old Court Road Suite 204
Randallstown, Maryland 21133

CLIA ID# 21D0215728

SANCTION: Directed Plan of Correction.

EFFECTIVE DATE: May 14, 2004

REASON: Unsuccessful participation in proficiency testing.

STATUS: Limitation of CLIA certificate and cancellation of approval to receive Medicare payment for the red blood cell (RBC) analyte.
SANCTION: Suspension of accreditation in disciplines of Chemistry and Point of Care Testing.

EFFECTIVE DATE: May 4, 2004

REASON: Suspension of the disciplines of Chemistry and Point of Care Testing for noncompliance with CAP Standards for Accreditation in Chemistry and Point of Care Testing as indicated by the seriousness and recurrence of deficiencies identified during a focused non-routine inspection on April 26, 2004.

STATUS: The laboratory initiated action to correct deficiencies. On August 31, 2004 suspension was lifted and Chemistry and Point of Care Testing were placed on probation. The laboratory is currently accredited with Chemistry and Point of Care Testing on probation.

Robert S. Fredericks, M.D., Director
Endocrine Associates
540 W. Plumb Lane, Suite 2A
Reno, Nevada 89509

CLIA ID# 29D0539692

SANCTION: Directed Plan of Correction.

EFFECTIVE DATE: November 4, 2004

REASON: Condition level non-compliance; unsuccessful participation in proficiency testing.

STATUS: Approval to receive Medicare payment for the subspecialty of routine chemistry cancelled on November 4, 2004 for a period not less than six months.
SANCTION: Accreditation with Conditions.

EFFECTIVE DATE: November 19, 2004

REASON: Accreditation with the condition of providing documentation due to the laboratory’s inability to correct space deficiencies, identified during the September 29, 2004 routine inspection, prior to re-accreditation. The laboratory must provide documentation to the CAP in September 2005 that space issues have been resolved.

STATUS: The laboratory implemented corrective action for all deficiencies. The laboratory is currently accredited.

Razia S. Rehman, M.D., Director
Cornell Clinicals Inc.
171 Elmora Avenue
Elizabeth, New Jersey 07202
CLIA ID# 31D0947675

SANCTION: Civil Money Penalty of $1,983.

EFFECTIVE DATE: July 9, 2004

REASON: Condition level non-compliance - immediate jeopardy.

STATUS: Laboratory ceased prothrombin time and INR testing.

Sushila Varadarajan, M.D., Director
Med Tech Clinical Laboratory Inc.
438 Ganttown Road, Suite B-8
Sewell, New Jersey 08080
CLIA ID# 31D1002581

SANCTION: Civil Money Penalty of $3,500.

EFFECTIVE DATE: July 27, 2004

REASON: Condition level non-compliance – immediate jeopardy.

Patric Y. Nassaux, M.D., Director  
Crownpoint Healthcare Facility  
Highway 371 & Navajo 9  
P.O. Box 358  
Crownpoint, New Mexico 87313  
**CLIA ID# 32D0536088**

**SANCTION:** Directed Plan of Correction.

**EFFECTIVE DATE:** September 11, 2004

**REASON:** Condition level non-compliance – Immediate Jeopardy.

Joseph Gardith, M.D., Director  
HemOnCare, PC  
2558 E 18th Street, Corner Avenue Z  
Brooklyn, New York 11234  
**CLIA ID# 33D0147881**

**SANCTION:** Civil Money Penalty of $487.50.

**EFFECTIVE DATE:** December 23, 2004

**REASON:** Condition-level noncompliance after denial of accreditation by COLA.

**STATUS:** Civil Money Penalty Paid.

New York University Medical Center  
Clinical Laboratories  
560 First Avenue Th-351  
New York, New York 10016  
**CLIA ID# 33D0653358 (CAP)**

**SANCTION:** Accreditation with Conditions.

**EFFECTIVE DATE:** October 14, 2004

**REASON:** Accredited with the condition of providing additional documentation to the CAP due to the laboratory’s inability to completely correct deficiencies, identified during the June 2, 2004 routine inspection, prior to re-accreditation. The laboratory will provide the required documentation in January 2005.

**STATUS:** The laboratory has initiated correction of all deficiencies. The laboratory is currently accredited.
Sound Shore Medical Center
Main Laboratory
New Rochelle, New York 10802
**CLIA ID# 33D0653713 (CAP)**

**SANCTION:** Accreditation with Conditions.

**EFFECTIVE DATE:** October 14, 2004

**REASON:** Accredited with the condition of providing the CAP with documentation of implementation of corrective actions taken in response to deficiencies identified during the March 30, 2004 routine inspection.

**STATUS:** The laboratory initiated corrective action and will provide the documentation at 6 months. The laboratory is currently accredited.

Kaleida Health Children’s Hospital
Pathology Laboratory
219 Bryant Street
Buffalo, New York 14222
**CLIA ID# 33D0654779 (CAP)**

**SANCTION:** Accreditation with Conditions.

**EFFECTIVE DATE:** July 27, 2004

**REASON:** Accredited with the condition of a non-routine inspection to be conducted in March 2005 due to the number and nature of the deficiencies identified at the February 25, 2004 routine inspection. The non-routine inspection will confirm sustained implementation of corrective actions.

**STATUS:** The laboratory implemented corrective action for all deficiencies. The laboratory is currently accredited.
SANCTION: Accreditation with Conditions.

EFFECTIVE DATE: October 15, 2004

REASON: Accredited with the condition of providing monthly reports of surgical pathology turnaround time to CAP based on deficiencies identified during routine inspection on January 23, 2004 and the response provided to those deficiencies.

STATUS: The laboratory has initiated corrective action and is providing the monthly reports. The laboratory is currently accredited.

Ezra Bendit, M.D., Director
1181 Old Country Road
Plainview, New York 11803

CLIA ID# 33D0680788

SANCTION: Civil Money Penalty of $1,300.

EFFECTIVE DATE: December 23, 2004

REASON: Condition-level noncompliance after denial of accreditation by COLA.

STATUS: Civil Money Penalty Paid.

Jill Waton, M.D., Director
Purcell Municipal Hospital
1500 N. Green Avenue
Purcell, Oklahoma 73080-1642

CLIA ID# 37D0470030

SANCTION: Directed Plan of Correction.

EFFECTIVE DATE: August 10, 2004

REASON: Condition level non-compliance – Immediate Jeopardy.

SANCTION: Directed Plan of Correction; Technical Assistance and Training.

EFFECTIVE DATE: July 27, 2004

REASON: Condition level non-compliance – Immediate Jeopardy; demonstration of unsuccessful participation proficiency testing.


Good Samaritan Regional Medical Center
Main Laboratory
700 E. Norwegian Street
Pottsville, Pennsylvania 17901-2798

CLIA ID# 39D0012193 (CAP)

SANCTION: Accreditation with Conditions.

EFFECTIVE DATE: August 18, 2004

REASON: Accredited with the condition of a non-routine inspection to be conducted in April 2005 due to the number of deficiencies and the quality of response to those deficiencies identified at the April 28, 2004 routine inspection. The non-routine inspection will confirm sustained implementation of corrective actions.

STATUS: The laboratory implemented corrective action for all deficiencies. The laboratory is currently accredited.
Hazelton Saint Joseph Medical Center Laboratory
North Church & Ninth Street
Hazelton, Pennsylvania  18201
**CLIA ID# 39D0012372 (CAP)**

**SANCTION:** Suspension of Accreditation in the discipline of Transfusion Medicine.

**EFFECTIVE DATE:** November 3, 2004

**REASON:** Suspension of the discipline of Transfusion Medicine for noncompliance with CAP Standards for Accreditation in Transfusion Medicine. Laboratory failed to provide satisfactory response to deficiencies identified during complaint inspection conducted September 22, 2004.

**STATUS:** The laboratory initiated further corrective actions to correct deficiencies. The laboratory is required to submit monthly progress reports to the CAP of implementation of corrective actions. The laboratory is currently accredited, with Transfusion Medicine suspended.

Warren General Hospital
2 Crescent Park
Warren, Pennsylvania  16365
**CLIA ID# 39D0183697 (CAP)**

**SANCTION:** Accreditation with Conditions.

**EFFECTIVE DATE:** September 7, 2004

**REASON:** Accredited with the condition of a non-routine inspection to be conducted in May 2005 due to the number and nature of deficiencies identified at the May 20, 2004 routine inspection. The non-routine inspection will confirm sustained implementation of correction actions.

**STATUS:** The laboratory implemented corrective action for all deficiencies. The laboratory is currently accredited.
SANCTION: Accreditation with Conditions.

EFFECTIVE DATE: August 25, 2004

REASON: Accredited with the condition of a non-routine inspection to be conducted in June 2005 due to limited number of records available at the initial inspection conducted on June 25, 2004. The laboratory had only begun testing at the time of the initial inspection.

STATUS: The laboratory provided appropriate responses to all deficiencies. The laboratory is currently accredited.

Axel Arroyo, M.D., Director
Laboratorio Clinico Hospital Damas, Inc.
2213 Ponce By Pass
Ponce, Puerto Rico  00717

CLIA ID# 40D0658169

SANCTION: Civil Money Penalty of $10,465.

EFFECTIVE DATE: October 28, 2004

REASON: Condition level non-compliance – Immediate Jeopardy.

Plaza Medical Center of Fort Worth
Main Laboratory
900 8th Avenue
Fort Worth, Texas  76104
CLIA ID# 45D0052440 (CAP)

SANCTION: Accreditation with Conditions.

EFFECTIVE DATE: May 6, 2004

REASON: Accredited with the condition of notifying the CAP of any delays in planned renovation of laboratory due to the laboratory’s inability to correct space deficiencies, identified during the March 4, 2004 routine inspection, prior to re-accreditation. The laboratory will also submit results of its March 2005 self-inspection.

STATUS: The laboratory has provided a plan for renovation. The laboratory is currently accredited.

Baylor All Saints Medical Center
Main Laboratory
1400 8th Ave
Fort Worth, Texas  76104-4110
CLIA ID# 45D0668698 (CAP)

SANCTION: Accreditation with Conditions.

EFFECTIVE DATE: September 10, 2004

REASON: Accredited with the condition of a non-routine inspection to be performed in June 2005 due to the laboratory’s inability to correct space deficiencies, identified during the June 18, 2004 routine inspection, prior to re-accreditation. The laboratory will also submit bi-monthly progress reports.

STATUS: The laboratory has provided a satisfactory plan for addressing the deficiencies. The laboratory is currently accredited.
Ennis Regional Medical Center Laboratory
801 West Lampasas
Ennis, Texas  75119
CLIA ID# 45D0680542 (CAP)

SANCTION:  Probation of Accreditation
EFFECTIVE DATE:  October 20, 2004
REASON:  Probation of the laboratory’s accreditation due to inadequate correction of deficiencies confirmed during non-routine inspection performed on June 16, 2004.
STATUS:  The laboratory corrected deficiencies, correction confirmed during non-routine inspection on December 2, 2004, and probation was lifted on January 4, 2005. The laboratory is currently accredited.

Nieva R. Ladrilllono, MS, MT., Director
Planned Parenthood of Southeast Virginia
425 West 20th Street Suite 6
Norfolk, Virginia  23517
CLIA ID# 49D0230416

SANCTION:  Directed Plan of Correction.
EFFECTIVE DATE:  January 17, 2004
REASON:  Unsuccessful participation in proficiency testing.

Harrisonburg Cytopathology
337 Cub Lane
Mac Gaheyville, Virginia  22840
CLIA ID# 49D0661086 (CAP)

SANCTION:  Probation of Accreditation
EFFECTIVE DATE:  October 20, 2004
REASON:  Probation of laboratory’s accreditation due to significant number and severity of deficiencies identified during non-routine inspection on October 5, 2004.
STATUS:  The laboratory initiated correction of deficiencies. Laboratory had non-routine inspection on January 19, 2005. The laboratory is currently accredited.
Kyle F. Fort, M.D., Director  
Greenbrier Valley Urology Associates, Inc.  
119 Maplewood Avenue at Fairlea  
Ronceverte, West Virginia  24970  
**CLIA ID# 51D0233762**

**SANCTION:** Directed Plan of Correction.

**EFFECTIVE DATE:** March 11, 2004

**REASON:** Unsuccessful participation in proficiency testing.

**STATUS:** Compliance achieved May 11, 2004.
The following was supplied by the State of New York under their CLIA Exempt Status:

Alfred Seipp, Director  
Vitamin Diagnostics Inc.  
RT #35 & Industrial Drive  
Cliffwood Beach, New Jersey  07735-6113  
CLIA ID# 31D0710366

SANCTION: Denial of Seipp’s application for a Director Certificate of Qualification.

EFFECTIVE DATE: July 6, 2004

REASON: Unwillingness or inability to fulfill the duties and responsibilities of director evidenced by deficiencies at two laboratories operating under his direction.

Milton Eke, Director  
TL Clinical Laboratory  
238 Rockaway Ave  
Valley Stream, New York  11582  
CLIA ID# 33D0155229

SANCTION: Denial of Eke’s application for a laboratory director Certificate of Qualification.

EFFECTIVE DATE: April 6, 2004

REASON: False representation of material on application.

Anne Platt, M.D., Director  
Enzo Clinical Labs, Inc.  
60 Executive Blvd  
Farmingdale, New York  11735-4716  
CLIA ID# 33D0159701

SANCTION: Civil penalty of $2000, and imposed plan of correction to ensure laboratory’s procedure for participation in proficiency testing (PT) effectively prevent sharing of results between two sites.

EFFECTIVE DATE: October 7, 2004

REASON: PT misrepresentation. The parent laboratory performed antigen detection analysis on streptococcus PT samples intended for processing by a separate facility under the same ownership, and in reporting results, misrepresented the location of actual testing and analyst who performed the testing.
Claude Neptune, Director
Pathlab
241 37th Street
Brooklyn, New York 11232
CLIA ID# 33D0654096

SANCTION: Letter of reprimand to laboratory director that imposes a requirement for Department approval prior to acceptance of a director position with a regulated facility.

EFFECTIVE DATE: February 25, 2004

REASON: PT misrepresentation. In reporting results for a toxicology PT challenge, the laboratory misrepresented the analyst who performed the test.

Charles Pavia, Director
Infectious Diseases Immundiagnostic Laboratory
Macy Pavillion W Medical Center
Valhalla, New York 10595
CLIA ID# 33D0927933

SANCTION: Denial of Pavia’s application for laboratory director Certificate of Qualification.

EFFECTIVE DATE: May 27, 2004

REASON: Unwillingness or inability to fulfill effectively the duties and responsibilities of a director as evidenced by deficiencies at a laboratory operating under his direction.

Gladys Ngozi Ibezim, Director
GLADZIM Medical & Scientific Lab, Inc.
215 Rockaway Avenue
Brooklyn, New York 11233
CLIA ID# 33D0995496

SANCTION: Denial of application for a laboratory certificate.

EFFECTIVE DATE: September 15, 2004

REASON: Unwillingness or unable to bring the laboratory into compliance with certificate requirements.
LABORATORIES WHOSE ACCREDITATION HAS BEEN WITHDRAWN OR REVOKED AND THE REASON FOR THE WITHDRAWAL OR REVOCATION.

Jamie Kapner, M.D., Director
10250 N 92nd Street Suite 100
Scottsdale, Arizona  85258
CLIA ID# 03D0530323 (COLA #15124)

SANCTION: Denial of Accreditation.
EFFECTIVE DATE: December 2, 2004
REASON: Failure to adhere to COLA imposed required improvements; failure to comply with reasonable requests of COLA.

Cyto Temps, Inc.
9520 Padgett Street, Suite 105
San Diego, California  92126-4442
CLIA ID# 05D0939434 (CAP)

SANCTION: Denial of Accreditation.
EFFECTIVE DATE: October 20, 2004
REASON: Non-compliance with CAP standards for Accreditation as evidenced by the number and severity of deficiencies identified during a routine inspection on June 11, 2004 and the inadequate actions to those deficiencies.

Oscar A. Soto, M.D., Director
Medical Arts Complex
4701 North Federal Highway
Fort Lauderdale, Florida  33308
CLIA ID# 10D0284154 (COLA #4562)

SANCTION: Denial of Accreditation.
EFFECTIVE DATE: June 2, 2004
REASON: Continuing to test an analyte, specialty or subspecialty after being directed by COLA to cease testing. Failure to meet proficiency testing requirements; Failure to adhere to COLA imposed required improvements; failure to comply with reasonable request of COLA.
World Diagnostic Medical Laboratory  
4111 SW 47th Ave# 331  
Davie, Florida  33314  
**CLIA ID# 10D1010037 (CAP)**  
SANCTION: Denial of Accreditation  
EFFECTIVE DATE: November 23, 2004  
REASON: Non-compliance with CAP Standards for Accreditation as evidenced by the number and severity of deficiencies identified during a non-routine inspection on November 19, 2004.

Lakewood Ranch Medical Center Laboratory  
8330 Lakewood Ranch Blvd.  
Lakewood Ranch, Florida  34202  
**CLIA ID# 10D1026767 (CAP)**  
SANCTION: Denial of Accreditation  
EFFECTIVE DATE: November 16, 2004  
REASON: Non-compliance with CAP Standard for Accreditation as evidenced by the number and severity of deficiencies identified during a non-routine inspection on November 8-10 2004.

Kolavennu Krishnaiah, PhD., Director  
Glass Clinical Laboratory  
2711 W. 183rd Street  
Homewood, Illinois  60430  
**CLIA ID# 14D0646517 (COLA# 15888)**  
SANCTION: Denial of Accreditation  
EFFECTIVE DATE: December 2, 2004  
REASON: Failure to adhere to COLA imposed required improvements; failure to comply with reasonable request of COLA
Federal Medical Center
Central Laboratory
3301 Leestown Road
Lexington, Kentucky 40511
**CLIA ID# 18D0682397 (CAP)**

SANCTION: Denial of Accreditation

EFFECTIVE DATE: November 16, 2004

REASON: Non-compliance with CAP Standards for Accreditation as evidenced by the number severity of deficiencies identified during a non-routine inspection on October 6, 2004.

Judith Hackett M.D., Director
1901 Leonidas Street
New Orleans, Louisiana 70118
**CLIA ID# 19D0459294 (COLA #11592)**

SANCTION: Denial of Accreditation

EFFECTIVE DATE: December 2, 2004

REASON: Failure to adhere to COLA imposed required improvements; failure to comply with reasonable request of COLA.

Alan Spires, M.D., Director
Mer Rouge Medical Center
301 Davenport Ave. P.O. Box 429
Mer Rouge, Louisiana 71261
**CLIA ID# 19D0464385 (COLA #11323)**

SANCTION: Denial of Accreditation

EFFECTIVE DATE: February 23, 2004

REASON: Continue to test an analyte specialty or subspecialty after being directed by COLA to cease testing because of failure to meet proficiency testing requirements. Failure to adhere to COLA imposed required improvements; failure to comply with reasonable request of COLA.
SANCTION: Denial of Accreditation

EFFECTIVE DATE: May 28, 2004

REASON: Non-compliance with CAP Standards for Accreditation as identified during a non-routine complaint inspection conducted on May 19, 2004. Issues related to laboratory directorship, reuse of cytology filters in violation of manufacturer’s instructions and violation of cytotechnologist workload limits.

Kenneth D. Asher, Director
Jackson Family Clinic
545 Broadridge Drive
Jackson, Missouri 63755-3001
CLIA ID# 26D0442079 (COLA #692)

SANCTION: Denial of Accreditation

EFFECTIVE DATE: February 23, 2004

REASON: Failure to adhere to COLA imposed required improvements; failure to comply with reasonable requests of COLA.

Edward Andujar M.D., Director
Alternacare
516 East Wood Street
Vineland, New Jersey 08360
CLIA ID# 31D0858401 (COLA 7537)

SANCTION: Denial of Accreditation

EFFECTIVE DATE: August 26, 2004

REASON: Failure to adhere to COLA imposed required improvements. Failure to comply with reasonable requests to COLA.
Hazelton General Hospital Laboratory  
700 E Broad Street  
Hazelton, Pennsylvania  
**CLIA ID# 39D0191367 (CAP)**

**SANCTION:** Denial of Accreditation  

**EFFECTIVE DATE:** September 24, 2004  

**REASON:** Noncompliance with CAP Standards for Accreditation as evidenced by the number and severity of deficiencies, as well as the number of recurrent deficiencies, identified during a non-routine complaint inspection conducted on May 4, 2004.

G.M. Gollauudi, M.D., Director  
Diabetes Center of the Southwest  
10 Desta Drive Suite 190  
Midland, Texas  79705-4514  
**CLIA ID# 45D0508756 (COLA #2452)**

**SANCTION:** Denial of Accreditation  

**EFFECTIVE DATE:** June 2, 2004  

**REASON:** Failure to adhere to COLA imposed required improvements; failure to comply with reasonable request of COLA.

Fernando Lombana, M.D., Director  
Tejas Medical & Dental Center  
2323 Wirt Road Suite F  
Houston, Texas  77055-1231  
**CLIA ID# 45D0876360 (COLA #7867)**

**SANCTION:** Denial of Accreditation  

**EFFECTIVE DATE:** December 6, 2004  

**REASON:** Failure to adhere to COLA imposed required improvements; failure to comply with reasonable requests of COLA.
6. **ALL APPEALS AND HEARING DECISIONS.**
For detailed information regarding the following listing see CLIA Hearing Decision Index at [http://www.cms.gov/clia/hearinggroup.asp](http://www.cms.gov/clia/hearinggroup.asp)

- **Immuno Biogene Inc.**
  - Charles Black, M.D., Director v. CMS
  - 23101 Sherman Place Suite 404
  - West Hills, California 91307
  - CLIA ID# 05D0542702

- **Millennium Clinical Laboratories**
  - Dom T. Salamanca, Director v. CMS
  - 401 South Flower Street
  - Burbank, California 91502
  - CLIA ID# 05D0672667

- **American Diagnostic Labs**
  - Luis Hernandez, M.D., Director v CMS
  - 9209 South Colima Road, Suite 2300
  - Whittier, California 90605
  - CLIA ID# 05D0954736

- **White Lake Family Medicine**
  - David Leszkowitz Director v. CMS
  - 9178 Highland Road Suite 1
  - White Lake, Michigan 48836-2032
  - CLIA ID# 23D0697765

- **Vijay Sakhula, M.D., Director v. CMS**
  - 146 14 Hillside Avenue
  - Jamaica, New York 11435
  - CLIA ID #33D0907221
7. A LIST OF LABORATORIES AGAINST WHICH CMS HAS BROUGHT SUIT UNDER SECTION 493.1846 AND THE REASON FOR THOSE ACTIONS.
8. A LIST OF LABORATORIES THAT HAVE BEEN EXCLUDED FROM PARTICIPATION IN MEDICARE OR MEDICAID AND THE REASON FOR EXCLUSION.

NONE
9. CORRECTION OF ANY ERRONEOUS STATEMENTS OF INFORMATION THAT APPEARED IN THE 2003 REGISTRY.

NONE
10. OTHER ACTIONS. THIS SECTION INCLUDES OTHER SPECIFIC INFORMATION THAT MAY BE USEFUL IN EVALUATING THE PERFORMANCE OF LABORATORIES, AS SPECIFIED IN 493 CFR 1859(A). IT ALSO INCLUDES INFORMATION PROVIDED BY CLIA EXEMPT STATES.

NONE
The following was supplied by the Office of the Inspector General:

Quest Diagnostics, Inc.
1 Malcolm Avenue
Teterboro, New Jersey   07608
Settlement date:   03/03/2004
ISSUE: False Claims

Medipath Expresss, Inc.
666 Plainsboro Road
Plainsboro, New Jersey   08302
Settlement date:   09/21/2004
ISSUE: False Claims

MR&S, Inc., d/b/a Atherotech, Inc.
201 London Parkway
Birmingham, Alabama   07816
Settlement date:   04/01/2004
ISSUE: False Claims

Health Line Clinical Laboratories Inc.
3601 West Alameda
Burbank, California   91505
Settlement date:   05/12/2004
ISSUE: False Claims

Balco Laboratories
1520 Gilbreth Road
Burlingame, California   94010
Settlement date:   09/03/2004
ISSUE: Unjust enrichment and payment by mistake of fact.