CLIA Annual Laboratory Registry Overview

1. CFR 493.1850 requires that once a year CMS make available to physicians and 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.

   a. In January a letter is sent to each CMS Operations Locations requesting any sanctions taken against a laboratory in the previous calendar year.

   b. Letters are also sent to the each Accreditation Organization (AO).

   c. Time frame – the CMS Operations Locations and AOs have 60 days to respond and submit actions to CMS Baltimore.

2. Once the information is received from the CMS Locations and the AOs, it has to be sorted and put in numerical order within each category. There are 10 regulatory sections.

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 certificate suspended, limited, or revoked, and the reason 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 off 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 A list of laboratories whose accreditation has been withdrawn or revoked and the reason for the withdrawal or decision.

6. All appeals and hearing decisions.

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 reasons for exclusion.

9. This Section is for “ Corrections of any Erroneous Statements of Information that Appeared in a previous Registry”.

10. Other Actions. This 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 status.

The Registry can also include SETTLEMENTS which is generally supplied by the Office of the Inspector General.

1. Once the CMS Operations Locations have finished input for the calendar year under review into the data system (AEM – ASPEN Enforcement Manager), a report is run that collates the information in numerical order and per section (1 through 10). All actions taken by the AOs must be entered into AEM manually.

2. A final Laboratory Registry report is run when all of the information is complete. This report is checked for accuracy by the CMS Locations, AOs, and CMS Baltimore prior to publication on the CLIA website.
1. LABORATORIES SUBJECT TO CLIA THAT HAVE BEEN CONVICTED, UNDER FEDERAL OR STATE LAWS RELATING TO FRAUD AND ABUSE, FALSE BILLING, OR KICKBACKS.

*** NO DATA FOUND ***
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.)

JOSEPH MACHUZAK, DIRECTOR
J M DERMATOLOGY
3124 WILLOW CREEK RD
PRESCOTT, AZ 86301
CLIA ID# 03D2147354

SANCTION: Cancel Medicare/Medicaid Approval
Suspension of CLIA Certificate
Revocation of CLIA Certificate

EFFECTIVE DATE: January 17, 2020
January 17, 2020
March 9, 2020

REASON: 2 Year Prohibition From Owning, Operating and Directing
Medicare Cancellation/Suspension
Condition Level Non-Compliance with IJ
Failure to Correct Deficiencies
Revocation of CLIA Certificate
Failure To Submit Acceptable POC or AOC
Lab Owner/Oper Prohibited From Owning Lab

STATUS: Revocation of CLIA Certificate

AFSHIN GABAYAN, MD, DIRECTOR
BEVERLY HILLS CANCER CENTER
8900 WILSHIRE BLVD
BEVERLY HILLS, CA 90211
CLIA ID# 05D1077766

SANCTION: Limitation of CLIA Certificate

EFFECTIVE DATE: January 10, 2020

REASON: Cancellation of Medicare Approval Suspension
Condition Level Non-Compliance
Unsuccessful PT
Limitation of CLIA Certificate

November 20, 2020

Unsuccessful PT

Laboratory voluntarily Ceased Testing

Limitation of CLIA Certificate

August 31, 2020

Condition Level Non-Compliance

Unsuccessful PT

Cancel Medicare/Medicaid Approval

January 21, 2020

March 6, 2020

Condition Level Non-Compliance

Revocation of CLIA Certificate
Marilyn McMilen MD, Director
Combined Physicians Lab
469 West Pleasant Street
Cynthiana, KY 41031
CLIA ID# 18D0648560

Sanction: Limitation of CLIA Certificate
Effective Date: October 7, 2020
Reason: Medicare Cancellation/Suspension
Condition: Level Non-Compliance
Unsuccessful PT
Failure to Correct Deficiencies
Status: Laboratory voluntarily Ceased Testing
Reason: Laboratory failed to provide documentation of passing routine or remedial PT.

Michael Zachareas, Director
New England Urology
900 Cummings Ctr
Beverly, MA 01915
CLIA ID# 22D1095814

Sanction: Limitation of CLIA Certificate
Effective Date: August 18, 2020
Reason: Suspension And Limitation Lifted
Status: Compliance Achieved
Reason: Reinstated HCG effective 11/19/2020.

Robert Black II, Director
Nevada Medical Clinic
900 S Adams
Nevada, MO 64772
CLIA ID# 26D0681861

Sanction: Limitation of CLIA Certificate
Effective Date: January 22, 2020
Reason: Unsuccessful PT
STEPHEN GODFREY, DIRECTOR
STOVER DIAGNOSTICS LABORATORIES, INC
1776 CROSSWINDS DR
WENTZVILLE, MO 63385
CLIA ID# 26D0691515

SANCTION:  
Cancel Medicare/Medicaid Approval  
Suspension of CLIA Certificate  
Revocation of CLIA Certificate

EFFECTIVE DATE:  
September 7, 2020  
September 7, 2020  
October 27, 2020

REASON:  
Cancellation of Medicare Approval Suspension  
Condition Level Non-Compliance with IJ  
Revocation of CLIA Certificate  
Lab Owner/Oper Prohibited From Owning Lab

STATUS:  
Revocation of CLIA Certificate

LUIS TUMIALAN, DIRECTOR
CLINLAB, INC
763 S NEW BALLAS ROAD, STE 160
SAINT LOUIS, MO 63141
CLIA ID# 26D0995726

SANCTION:  
Cancel Medicare/Medicaid Approval  
Revocation of CLIA Certificate

EFFECTIVE DATE:  
February 3, 2020  
March 29, 2020

REASON:  
2 Year Prohibition From Owning, Operating and Directing  
Condition Level Non-Compliance with IJ  
Failure to Correct Deficiencies  
Revocation of CLIA Certificate  
Failure To Submit Acceptable POC or AOC  
Lab Owner/Oper Prohibited From Owning Lab

STATUS:  
Revocation of CLIA Certificate
DAVID SMALLEY, DIRECTOR
GAMMA HEALTHCARE, INC - POPLAR BLUFF
1717 WEST MAUD ST
POPLAR BLUFF, MO 63901
CLIA ID# 26D1041510

SANCTION: Suspension of CLIA Certificate
EFFECTIVE DATE: October 26, 2020
REASON: Condition Level Non-Compliance with IJ
Failure to Correct Deficiencies
Failure To Submit Acceptable POC or AOC
STATUS: Revocation Pending Hearing
Appeal filed by Laboratory

BURSON, MICHAEL, & WALZ, STACY DIRECTOR
GAMMA HEALTHCARE INC - SPRINGFIELD 228 E PRIMROSE
SPRINGFIELD, MO 65807
CLIA ID# 26D2102945

SANCTION: Suspension of CLIA Certificate
EFFECTIVE DATE: October 26, 2020
REASON: Condition Level Non-Compliance with IJ
Failure to Correct Deficiencies
Failure To Submit Acceptable POC or AOC
STATUS: Revocation Pending Hearing
Appeal filed by Laboratory

ANTON SOHN, DIRECTOR
R E D LABORATORIES
1664 N VIRGINIA ST MS554 BLDG 160
RENO, NV 89557
CLIA ID# 29D2019771

SANCTION: Revocation of CLIA Certificate
EFFECTIVE DATE: September 29, 2020
REASON: 2 Year Prohibition From Owning, Operating and Directing
Medicare Cancellation/Suspension
Condition Level Non-Compliance
Revocation of CLIA Certificate
Failure To Submit Acceptable POC or AOC
Lab Owner/Oper Prohibited From Owning Lab
STATUS: Hearing Decision Sustained CMS Sanc Determ
GLENN STALL, DIRECTOR
RALEIGH ENDOCRINE ASSOCIATES
2709 BLUE RIDGE ROAD, SUITE 320
RALEIGH, NC 27607
CLIA ID# 34D0240409

SANCTION: Limitation of CLIA Certificate
EFFECTIVE DATE: October 23, 2020
REASON: Unsuccessful PT
STATUS: Laboratory voluntarily Ceased Testing

STEPHEN BAUCH, DIRECTOR
MEMPHIS CHILDREN'S CLINIC
6385 STAGE RD, SUITE 2
BARTLETT, TN 38134
CLIA ID# 44D0315095

SANCTION: Limitation of CLIA Certificate
EFFECTIVE DATE: March 20, 2020
REASON: Condition Level Non-Compliance
Improper PT Testing Referral Activities

OLUWASEUN HEINKEL, DIRECTOR
MEMPHIS CHILDREN'S CLINIC
6615 KIRBY CENTER COVE
MEMPHIS, TN 38115
CLIA ID# 44D0677022

SANCTION: Limitation of CLIA Certificate
EFFECTIVE DATE: March 20, 2020
REASON: Condition Level Non-Compliance
Improper PT Testing Referral Activities

OLUWASEUN HEINKEL, DIRECTOR
MEMPHIS CHILDREN'S CLINIC
1129 HALE ROAD
MEMPHIS, TN 38116
CLIA ID# 44D0677246

SANCTION: Limitation of CLIA Certificate
EFFECTIVE DATE: March 20, 2020
REASON: Condition Level Non-Compliance
Improper PT Testing Referral Activities
TERRY GESHE, DIRECTOR
MEMPHIS CHILDREN’s CLINIC
7705 POPLAR AVE SUITE 230 BLDG B
GERMANTOWN, TN 38138
CLIA ID# 44D0677386

SANCTION: Limitation of CLIA Certificate
EFFECTIVE DATE: March 20, 2020
REASON: Condition Level Non-Compliance
 improper PT Testing Referral Activities

STEPHEN BAUCH MD, DIRECTOR
MEMPHIS CHILDREN’S CLINIC PLLC
AKINGMEMPHISCHELDRENSCOM
3155 KIRBY WHITTEN ROAD
BARTLETT, TN 38134
CLIA ID# 44D0957613

SANCTION: Limitation of CLIA Certificate
EFFECTIVE DATE: March 20, 2020
REASON: Condition Level Non-Compliance with IJ
Unsuccessful PT

JAMSHED HAQ, DIRECTOR
TENNESSEE VALLEY REGIONAL LABORATORY
DBA SPRINGS MEDICAL LAB
7349 MIDDLEBROOK PIKE
KNOXVILLE, TN 37909
CLIA ID# 44D2062571

SANCTION: Cancel Medicare/Medicaid Approval
Revocation of CLIA Certificate
EFFECTIVE DATE: May 4, 2020
REASON: 2 Year Prohibition From Owning, Operating and Directing
Condition Level Non-Compliance
Failure to Correct Deficiencies
Revocation of CLIA Certificate
Failure To Submit Acceptable POC or AOC
STATUS: Revocation of CLIA Certificate
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.

*** NO DATA FOUND ***
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

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MICHELE ASTARITA, DIRECTOR
ONCOLOGY & RADIATION ASSOCIATES PA
3659 S MIAMI AVE STE 2001
MIAMI, FL 33133
CLIA ID# 10D0880678

SANCTION: Directed Plan of Correction (DPOC)
Suspension of Part of Medicare/Medicaid

EFFECTIVE DATE: November 20, 2020
November 20, 2020

REASON: Unsuccessful PT

STATUS: Laboratory voluntarily Ceased Testing

ALAN PETERSON, DIRECTOR
ST MARY’S HOSPITAL
701 LEWISTON ST
COTTONWOOD, ID 83522
CLIA ID# 13D0521144

SANCTION: Directed Plan of Correction (DPOC)
Suspension of Part of Medicare/Medicaid

EFFECTIVE DATE: August 31, 2020
August 31, 2020

REASON: Condition Level Non-Compliance
Unsuccessful PT

STEPHEN RUBY M D, DIRECTOR
DUPAGE MEDICAL GROUP- TINLEY PK LAB
17495 S LAGRANGE RD
TINLEY PARK, IL 60487
CLIA ID# 14D0420182

SANCTION: Civil Money Penalty

EFFECTIVE DATE: September 18, 2020

REASON: Improper PT Testing Referral Activities

STATUS: Compliance Achieved
SANCTION: Civil Money Penalty
EFFECTIVE DATE: October 5, 2020
REASON: Improper PT Testing Referral Activities
STATUS: Compliance Achieved

SANCTION: Civil Money Penalty
Directed Portion Plan of Correction (DPPOC)
Directed Plan of Correction (DPOC)
EFFECTIVE DATE: January 21, 2020
January 21, 2020
February 21, 2020
REASON: Condition Level Non-Compliance
STATUS: Revocation of CLIA Certificate

SANCTION: Directed Plan of Correction (DPOC)
Suspension of Part of Medicare/Medicaid
EFFECTIVE DATE: October 7, 2020
October 7, 2020
REASON: Condition Level Non-Compliance
Unsuccessful PT
Failure to Correct Deficiencies
STATUS: Compliance Achieved
Laboratory voluntarily Ceased Testing
REASON: Laboratory failed to provide documentation of passing routine or remedial PT
PREETPAL SIDHU, DIRECTOR
OWENSBORO MEDICAL PRACTICE LABORATORY
1200 BRECKENRIDGE STREET
OWENSBORO, KY 42303
CLIA ID# 18D0989820

SANCTION: Directed Plan of Correction (DPOC)
EFFECTIVE DATE: September 18, 2020
REASON: Condition Level Non-Compliance
Unsuccessful PT
STATUS: Laboratory voluntarily Ceased Testing

PATRICK WALKER, DIRECTOR
HOUMA HEALTH CLINIC
827 BAYOU GARDENS BLVD
HOUMA, LA 70364
CLIA ID# 19D1000384

SANCTION: Directed Plan of Correction (DPOC)
EFFECTIVE DATE: February 24, 2020
REASON: Condition Level Non-Compliance
STATUS: Compliance Achieved

MICHAEL ZACHAREAS, DIRECTOR
NEW ENGLAND UROLOGY
900 CUMMINGS CTR
BEVERLY, MA 01915
CLIA ID# 22D1095814

SANCTION: Directed Plan of Correction (DPOC)
Suspension of All of Medicare/Medicaid
EFFECTIVE DATE: August 18, 2020
August 18, 2020
REASON: Unsuccessful PT
STATUS: Suspension And Limitation Lifted
Compliance Achieved
REASON: Reinstated HCG effective 11/19/2020
JULIETA TABLANTE-BLANCO, DIRECTOR
SPECTRUM HEALTH BUTTERWORTH HOSPITAL LABORATORY
100 MICHIGAN STREET NE
GRAND RAPIDS, MI 49503
CLIA ID# 23D0380113

SANCTION: Civil Money Penalty
EFFECTIVE DATE: March 21, 2020
REASON: Improper PT Testing Referral Activities
STATUS: Compliance Achieved

ANDREA TERRELL, DIRECTOR
NEURO PAIN CONSULTANTS PC
26154 WOODWARD AVENUE SUITE 4
ROYAL OAK, MI 48067
CLIA ID# 23D1057542

SANCTION: Civil Money Penalty
EFFECTIVE DATE: October 28, 2020
REASON: Improper PT Testing Referral Activities
STATUS: Compliance Achieved

JULIETA TABLANTE-BLANCO, DIRECTOR
SPECTRUM HEALTH REGIONAL LABORATORY
35 MICHIGAN STREET
GRAND RAPIDS, MI 49503
CLIA ID# 23D2035129

SANCTION: Civil Money Penalty
Directed Plan of Correction (DPOC)
EFFECTIVE DATE: March 21, 2020
September 2, 2020
REASON: Improper PT Testing Referral Activities
STATUS: Compliance Achieved
KENNETH SIMKOWSKI, DIRECTOR
RPPC LABS LLC
26154 WOODWARD AVENUE SUITE 5
ROYAL OAK, MI 48067
CLIA ID# 23D2113189

SANCTION: Civil Money Penalty
EFFECTIVE DATE: October 28, 2020
REASON: Improper PT Testing Referral Activities
STATUS: Compliance Achieved

MICHAEL SMITH, DIRECTOR
CLINICAL CONNECT LABORATORIES, LLC
26154 WOODWARD AVENUE SUITE 1
ROYAL OAK, MI 48067
CLIA ID# 23D2119597

SANCTION: Civil Money Penalty
EFFECTIVE DATE: October 28, 2020
REASON: Improper PT Testing Referral Activities
STATUS: Compliance Achieved

ANDREA TERRELL, DIRECTOR
SYNCHRONIZED LAB SERVICES, LLC
26154 WOODWARD AVENUE SUITE 6
ROYAL OAK, MI 48067
CLIA ID# 23D2144369

SANCTION: Civil Money Penalty
EFFECTIVE DATE: October 28, 2020
REASON: Improper PT Testing Referral Activities
STATUS: Compliance Achieved
TODD KENDALL, DIRECTOR
GEORGE REGIONAL HOSPITAL
859 WINTER STREET
LUCEDALE, MS 39452
CLIA ID# 25D0672386

SANCTION: Directed Plan of Correction (DPOC)
EFFECTIVE DATE: December 21, 2020
REASON: Condition Level Non-Compliance
Unsuccessful PT
STATUS: Compliance Achieved

DELIA SMITH, DIRECTOR
MEDICAL ASSOCIATES OF VICKSBURG
2080 S FRONTAGE ROAD SUITE 100
VICKSBURG, MS 39180
CLIA ID# 25D1086495

SANCTION: Directed Plan of Correction (DPOC)
EFFECTIVE DATE: December 2, 2020
REASON: Condition Level Non-Compliance
Unsuccessful PT
STATUS: Compliance Achieved

ROBERT BLACK II, DIRECTOR
NEVADA MEDICAL CLINIC
900 S ADAMS
NEVADA, MO 64772
CLIA ID# 26D0681861

SANCTION: Directed Plan of Correction (DPOC)
EFFECTIVE DATE: January 22, 2020
REASON: Unsuccessful PT
STOVER DIAGNOSTICS LABORATORIES, INC
1776 CROSSWINDS DR
WENTZVILLE, MO 63385
CLIA ID# 26D0691515

SANCTION: Civil Money Penalty
EFFECTIVE DATE: September 2, 2020
REASON: Cancellation of Medicare Approval Suspension
Condition Level Non-Compliance with IJ
Failure to Correct Deficiencies
Revocation of CLIA Certificate

LUIS TUMIALAN, DIRECTOR
CLINLAB, INC
763 S NEW BALLAS ROAD, STE 160
SAINT LOUIS, MO 63141
CLIA ID# 26D0995726

SANCTION: Suspension of Part of Medicare/Medicaid
Directed Portion Plan of Correction (DPPOC)
EFFECTIVE DATE: January 25, 2020
February 8, 2020
REASON: Cancellation of Medicare Approval Suspension
Condition Level Non-Compliance with IJ
Failure to Correct Deficiencies
Failure To Submit Acceptable POC or AOC

GLENN STALL, DIRECTOR
RALEIGH ENDOCRINE ASSOCIATES
2709 BLUE RIDGE ROAD, SUITE 320
RALEIGH, NC 27607
CLIA ID# 34D0240409

SANCTION: Directed Plan of Correction (DPOC)
Suspension of Part of Medicare/Medicaid
EFFECTIVE DATE: October 23, 2020
October 23, 2020
REASON: Unsuccessful PT
STATUS: Laboratory voluntarily Ceased Testing
ARUNDHATI CHATTERJEE, DIRECTOR
LABCORP OF AMERICA HOLDINGS
1912 TW ALEXANDER DRIVE
RESEARCH TRIANGLE PARK, NC 27709
CLIA ID# 34D0655205

SANCTION: Civil Money Penalty
Directed Plan of Correction (DPOC)

EFFECTIVE DATE: January 31, 2020
January 31, 2020

REASON: Improper PT Testing Referral Activities

STATUS: Appeal Filed By Laboratory
Hearing Decision Sustained CMS Sanc Determ

JARED SCHMIDT, DIRECTOR
PATHOLOGY CONSULTANTS PC MAIN LABORATORY
3502 FRANKLIN AVE
BISMARCK, ND 58503
CLIA ID# 35D0408903

SANCTION: Civil Money Penalty
Directed Plan of Correction (DPOC)
Directed Portion Plan of Correction (DPPOC)

EFFECTIVE DATE: January 30, 2020
February 9, 2020
February 9, 2020

REASON: Improper PT Testing Referral Activities

STATUS: Compliance Achieved

SALEM SHAHIN, DIRECTOR
DR SALEM SHAHIN CLINIC
1219 KNOLL ST
WILLISTON, ND 58801
CLIA ID# 35D0409289

SANCTION: Civil Money Penalty

EFFECTIVE DATE: January 8, 2020

REASON: Improper PT Testing Referral Activities

STATUS: Compliance Achieved
JOHN ANDELIN MD, DIRECTOR
MERCY MEDICAL CENTER OF WILLISTON
1301 15TH AVE W
WILLISTON, ND 58801
CLIA ID# 35D0409305

SANCTION: Civil Money Penalty
Directed Plan of Correction (DPOC)
Directed Portion Plan of Correction (DPPOC)

EFFECTIVE DATE:
January 8, 2020
January 18, 2020
January 18, 2020

REASON: Improper PT Testing Referral Activities

STATUS: Compliance Achieved

JARED SCHMIDT, DIRECTOR
PATHOLOGY CONSULTANTS, PC PHYSICIAN OFFICE LAB
900 E BROADWAY
BISMARCK, ND 58501
CLIA ID# 35D2002387

SANCTION: Civil Money Penalty
Directed Plan of Correction (DPOC)
Directed Portion Plan of Correction (DPPOC)

EFFECTIVE DATE:
January 30, 2020
February 9, 2020
February 9, 2020

REASON: Improper PT Testing Referral Activities

STATUS: Compliance Achieved

STEPHEN BAUCH, DIRECTOR
MEMPHIS CHILDREN'S CLINIC
6385 STAGE RD, SUITE 2
BARTLETT, TN 38134
CLIA ID# 44D0315095

SANCTION: Directed Plan of Correction (DPOC)
Civil Money Penalty

EFFECTIVE DATE:
February 20, 2020
March 20, 2020

REASON: Condition Level Non-Compliance
Improper PT Testing Referral Activities
OLUWASEUN HEINKEL, DIRECTOR
MEMPHIS CHILDRENS CLINIC
1129 HALE ROAD
MEMPHIS, TN 38116
CLIA ID# 44D0677246

SANCTION: Directed Plan of Correction (DPOC)
Civil Money Penalty

EFFECTIVE DATE: March 20, 2020

REASON: Condition Level Non-Compliance
Improper PT Testing Referral Activities

TERRY GESHKE, DIRECTOR
MEMPHIS CHILDRENS CLINIC
7705 POPLAR AVE SUITE 230 BLDG B
GERMANTOWN, TN 38138
CLIA ID# 44D0677386

SANCTION: Directed Plan of Correction (DPOC)
Civil Money Penalty

EFFECTIVE DATE: March 20, 2020

REASON: Condition Level Non-Compliance
Improper PT Testing Referral Activities
SANCTION: Directed Plan of Correction (DPOC)
Civil Money Penalty

EFFECTIVE DATE: February 20, 2020
March 20, 2020

REASON: Condition Level Non-Compliance
Improper PT Testing Referral Activities

JERRY DEPRIEST, DIRECTOR
COMANCHE COUNTY MEDICAL CENTER COMPANY
D/B/A COMANCHE COUNTY MEDICAL CENTER
10201 HIGHWAY 16 NORTH
COMANCHE, TX 76442
CLIA ID# 45D0677527

SANCTION: Directed Plan of Correction (DPOC)

EFFECTIVE DATE: February 3, 2020

REASON: Condition Level Non-Compliance

STATUS: Compliance Achieved

SHAHAB KHAN, DIRECTOR
NORTH HOUSTON MEDICINE, TUMOR & BLOOD CLINIC, PA
1631 NORTH LOOP WEST, #100
HOUSTON, TX 77008
CLIA ID# 45D0926410

SANCTION: Directed Plan of Correction (DPOC)

EFFECTIVE DATE: February 17, 2020

REASON: Condition Level Non-Compliance
Unsuccessful PT

STATUS: Compliance Achieved
ANDREW CHUNG, DIRECTOR
ANDREW CHUNG MD, PLLC
3600 GASTON AVE #755
DALLAS, TX 75246
CLIA ID# 45D2030207

SANCTION: Directed Plan of Correction (DPOC)
EFFECTIVE DATE: January 29, 2020
REASON: Condition Level Non-Compliance with IJ
STATUS: Compliance Achieved

PATRICIA BAKER, DIRECTOR
QUALITY METRICS LABORATORIES, LLC
1860 CROWN DR SUITE 1408
DALLAS, TX 75234
CLIA ID# 45D2105931

SANCTION: Directed Plan of Correction (DPOC)
EFFECTIVE DATE: October 1, 2020
REASON: Condition Level Non-Compliance with IJ

JONATHAN STEIN, DIRECTOR
ALTRU DIAGNOSTICS INC
8562 KATY FREEWAY SUITE 152
HOUSTON, TX 77024
CLIA ID# 45D2128678

SANCTION: Directed Plan of Correction (DPOC)
EFFECTIVE DATE: October 29, 2020
REASON: Condition Level Non-Compliance with IJ
PATRICK GARDNER, DIRECTOR
FROEDTERT & THE MEDICAL COLLEGE OF WISCONSIN
COMMUNITY PHYSICIANS
1700 W PARADISE DR
WEST BEND, WI 53095
CLIA ID# 52D0678401

SANCTION: Civil Money Penalty
EFFECTIVE DATE: August 25, 2020
REASON: Improper PT Testing Referral Activities
STATUS: Compliance Achieved

PATRICK GARDNER, DIRECTOR
FROEDTERT AND MEDICAL COLLEGE COMMUNITY PHYSICIANS
- MEQUON 1
11430 N PORT WASHINGTON ROAD
MEQUON, WI 53092
CLIA ID# 52D2135321

SANCTION: Civil Money Penalty
EFFECTIVE DATE: October 15, 2020
REASON: Improper PT Testing Referral Activities
STATUS: Compliance Achieved

ERIC EBERTS, DIRECTOR
WOMEN'S CARE OF WISCONSIN
200 THEDA CLARK MEDICAL PLAZA SUITE 130
NEENAH, WI 54956
CLIA ID# 52D2149063

SANCTION: Civil Money Penalty
Directed Plan of Correction (DPOC)
EFFECTIVE DATE: January 31, 2020
January 31, 2020
REASON: Improper PT Testing Referral Activities
STATUS: Compliance Achieved
5. LABORATORIES WHOSE ACCREDITATION HAS BEEN WITHDRAWN OR REVOKED AND THE REASON FOR THE
WITHDRAWAL OR REVOCATION. (INCLUDES ALL OTHER ADVERSE ACTIONS TAKEN BY THE ACCREDITATION
ORGANIZATIONS)

NAVEEN LOBO, DIRECTOR
CANCER CARE CENTER
1310 14TH AVENUE SE
DECATUR, AL 35601
CLIA ID# 01D2019775 (COLA)

SANCTION: Cease Testing for Chloride
EFFECTIVE DATE: 12/14/2020
REASON: Non-Compliance Due to Unsuccessful Participation in Proficiency Testing
STATUS: As of 12/31/2020 Cease Testing Still in Effect

ARTHUR SITELMAN, DIRECTOR
SURGICAL SPECIALITY HOSPITAL OF ARIZONA, LLC
6501 N 19TH AVE
PHOENIX, AZ 85015
CLIA ID# 03D0057192 (COLA)

SANCTION: Cease Testing for Chloride
EFFECTIVE DATE: 11/24/2020
REASON: Non-Compliance Due to Unsuccessful Participation in Proficiency Testing
STATUS: As of 12/31/2020 Cease Testing Still in Effect

DAVID POPE, DIRECTOR
CONWAY REGIONAL MEDICAL CENTER
2302 COLLEGE AVENUE
CONWAY, AR 72032
CLIA ID# 04D0466269 (CAP)

SANCTION: Cease Testing for IgA
EFFECTIVE DATE: 10/20/2020
REASON: Non-Compliance Due to Unsuccessful Performance in Proficiency Testing
STATUS: As of 12/31/2020, Cease Testing Still in Effect
TOBI QUINTO, DIRECTOR
ORTHOPAEDIC INSTITUTE FOR CHILDREN
403 W. ADAMS BLVD.
LOS ANGELES, CA 90007
CLIA ID# 05D0540798 (TJC)

SANCTION: Voluntary Cease Testing for Sodium
EFFECTIVE DATE: 08/05/2020
REASON: Non-Compliance Due to Unsuccessful Participation in Proficiency Testing
STATUS: As of 12/31/2020 Cease Testing Still in Effect

SHARON YEE FACP, DIRECTOR
SHAPIRO, STAFFORD, YEE & POLANSKY, P C
622 W DUARTE ROAD #202
ARCADIA, CA 91007
CLIA ID# 05D0555273 (COLA)

SANCTION: Cease Testing for White Blood Cell Differential (WBC Diff)
EFFECTIVE DATE: 07/24/2020
REASON: Non-Compliance Due to Unsuccessful Participation in Proficiency Testing
STATUS: As of 12/31/2020 Cease Testing Still in Effect

SHAHIN SAMIMI MD, DIRECTOR
SOUTH COAST GLOBAL MEDICAL CENTER
2701 S BRISTOL STREET
SANTA ANA, CA 92704
CLIA ID# 05D0581023 (TJC)

SANCTION: Cease Testing for Partial Thromboplastin Time
EFFECTIVE DATE: 10/19/2020
REASON: Non-Compliance Due to Unsuccessful Participation in Proficiency Testing
STATUS: As of 12/31/20 Cease Testing still in effect
YAO SCHMIDT, DIRECTOR
SIERRA VIEW MEDICAL CENTER LAB
465 W PUTNAM AVE
PORTERVILLE, CA 93257
CLIA ID# 05D0585503 (TJC)

SANCTION:          Voluntary Cease Testing for Creatine Kinase Isoenzyme
EFFECTIVE DATE:    09/09/2020
REASON:            Non-Compliance Due to Unsuccessful Participation in Proficiency Testing
STATUS:            As of 12/31/2020 Cease Testing still in effect

DAVID SU, DIRECTOR
DAVID K SU MD
600 N GARFIELD AVE STE 305
MONTEREY PARK, CA 91754
CLIA ID# 05D0866548 (COLA)

SANCTION:          Cease Testing for Glucose, Sodium, BUN
EFFECTIVE DATE:    06/29/2020
REASON:            Non-Compliance Due to Unsuccessful Participation in Proficiency Testing
STATUS:            On 7/16/2020 Tests were Deleted from Menu

SAM NAJMABADI, DIRECTOR
CENTER FOR REPRODUCTIVE HEALTH AND GYNECOLOGY
99 N LA CIENEGA BLVD STE 109
BEVERLY HILLS, CA 90211
CLIA ID# 05D0954752 (CAP)

SANCTION:          Probation
EFFECTIVE DATE:    3/25/2020
REASON:            Quality and Severity of Deficiencies Is Significant Enough to Question Ability to Sustain Corrections;Corrective Action Fails to Support Implementation and Prevention of Recurrence in One or More Areas of the Laboratory
STATUS:            Removed from Probation on 09/23/2020
SEAN LEONI, DIRECTOR
PHYSICIANS OFFICE LABORATORY, SEAN LEONI, MD
16661 VENTURA BOULEVARD, SUITE #604
ENCINO, CA 91436
CLIA ID# 05D1005949 (COLA)

SANCTION: Denial of Accreditation
EFFECTIVE DATE: 06/17/2020
REASON: Failure to Permit a COLA On-Site Survey or Obstruct the Survey Process
STATUS: No Longer Accredited by COLA

DAVIDER DHILLON, DIRECTOR
ADVENTIST HEALTH AND RIDEOUT
726 4TH STREET
MARYSVILLE, CA 95901
CLIA ID# 05D1076598 (CAP)

SANCTION: Cease Testing for pO2
EFFECTIVE DATE: 4/11/2020
REASON: Non-Compliance Due to Unsuccessful Performance in Proficiency Testing
STATUS: Allowed to Resume Testing on 07/08/2020

DAVIDER DHILLON, DIRECTOR
ADVENTIST HEALTH AND RIDEOUT
726 4TH STREET
MARYSVILLE, CA 95901
CLIA ID# 05D1076598 (CAP)

SANCTION: Cease Testing for pCO2
EFFECTIVE DATE: 8/22/2020
REASON: Non-Compliance Due to Unsuccessful Performance in Proficiency Testing
STATUS: Allowed to Resume Testing on 11/02/2020
Cease Testing for Thyroid Stimulating Hormone (TSH), and Thyroxine, Free (FT4)
12/14/2020
Non-Compliance Due to Unsuccessful Participation in Proficiency Testing
As of 12/31/2020 Cease Testing Still in Effect

01/09/2020
Non-Compliance Due to Unsuccessful Participation in Proficiency Testing
As of 12/31/2020 Cease Testing Still in Effect

Cease Testing for Creatine Kinase Isoenzyme
01/16/2020
Non-Compliance Due to Unsuccessful Participation in Proficiency Testing
As of 12/31/20 Cease Testing still in effect
<table>
<thead>
<tr>
<th>Laboratory Name</th>
<th>SANCTION</th>
<th>EFFECTIVE DATE</th>
<th>REASON</th>
<th>STATUS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical Associates of West Florida LLP</td>
<td>Cease Testing for Alanine Aminotransferase (ALT) (SGPT), Creatine Kinase (CK)</td>
<td>07/24/2020</td>
<td>Non-Compliance Due to Unsuccessful Participation in Proficiency Testing</td>
<td>As of 12/31/2020 Cease Testing Still in Effect</td>
</tr>
<tr>
<td>William Brent Young MD PA</td>
<td>Cease Testing for Urea (BUN)</td>
<td>04/08/2020</td>
<td>Non-Compliance Due to Unsuccessful Participation in Proficiency Testing</td>
<td>Test was Reinstated on 10/13/2020</td>
</tr>
<tr>
<td>University of Miami-CHDS Pediatrics Associates</td>
<td>Cease Testing for Hematocrit, Hemoglobin, Platelet Count, Red Blood Cell Count (Erythrocyte Count) (RBC), White Blood Cell Count (Leukocyte Count) (WBC), White Blood Cell Differential (WBC Diff)</td>
<td>01/15/2020</td>
<td>Non-Compliance Due to Unsuccessful Participation in Proficiency Testing</td>
<td>Withdrew 10/19/20 Prior to Reinstatement No Longer Accredited by COLA</td>
</tr>
</tbody>
</table>
DAVID RUGGIERI, DIRECTOR
CENTER FOR HEALTH OF CHARLOTTE PA
1107 W MARION AVE STE 116
PUNTA GORDA, FL 33950
CLIA ID# 10D1102530 (COLA)

SANCTION: Cease Testing for Chloride
EFFECTIVE DATE: 06/04/2020
REASON: Non-Compliance Due to Unsuccessful Participation in Proficiency Testing
STATUS: As of 12/31/2020 Cease Testing Still in Effect

DAVID RUGGIERI, DIRECTOR
CENTER FOR HEALTH OF CHARLOTTE PA
1107 W MARION AVE STE 116
PUNTA GORDA, FL 33950
CLIA ID# 10D1102530 (COLA)

SANCTION: Cease Testing for Creatine Kinase MB Fraction (CKMB)
EFFECTIVE DATE: 11/24/2020
REASON: Non-Compliance Due to Unsuccessful Participation in Proficiency Testing
STATUS: As of 12/31/2020 Cease Testing Still in Effect

CHRISTINA KOVACS, DIRECTOR
BRANDON REGIONAL HOSPITAL EMERGENCY CARE
3065 JAMES L REDMAN PKWY
PLANT CITY, FL 33567
CLIA ID# 10D2043927 (CAP)

SANCTION: Cease Testing for Compatibility Testing
EFFECTIVE DATE: 10/29/2020
REASON: Non-Compliance Due to Unsuccessful Participation in Proficiency Testing
STATUS: Allowed to resume testing on 12/02/2020
MARJAN MIRZABEIGI, DIRECTOR
ATLANTIC BIOTECH LLC
1501 GREEN RD STE A
POMPANO BEACH, FL 33064 CLIA ID# 10D2087683 (COLA)

SANCTION: Cease Testing for HCG, Beta, Serum, Quantitative, Thyroxine (T4), Sodium, Potassium, Magnesium, Amylase, Alkaline Phosphatase (ALP), Alanine Aminotransferase (ALT) (SGPT), Cortisol, Uric Acid, Urea (BUN), Cholesterol, Chloride, Bilirubin, Total, Lactate Dehydrogenase (LDH), Triglyceride, Protein, Total, Aspartate Aminotransferase (AST) (SGOT), Albumin, Thyroid Stimulating Hormone (TSH), Triiodothyronine (T3), T Uptake (TU), Glucose, Creatinine, Creatine Kinase (CK), Calcium, Total, Iron, Thyroxine, Free (FT4), Prothrombin Time (PT), Activated Partial Thromboplastin Time (APTT), Fibrinogen, White Blood Cell Differential (WBC Diff)

EFFECTIVE DATE: 04/24/2020

REASON: Non-Compliance Due to Unsuccessful Participation in Proficiency Testing


PATRICK BUNYI, DIRECTOR
ACE BIOMEDICAL LABS LLC
3726 BEACH BLVD
JACKSONVILLE, FL 32207
CLIA ID# 10D2124965 (COLA)

SANCTION: Cease Testing for FT4, TSH, HDL Cholesterol

EFFECTIVE DATE: 03/21/2020

REASON: Non-Compliance Due to Unsuccessful Participation in Proficiency Testing

STATUS: FT4, TSH were Reinstated on 10/14/2020
As of 12/31/2020 Cease Testing for HDL Cholesterol Still in Effect

YENHUI CHANG, DIRECTOR
SEQUENTIAL GENETICS LLC
12105 28TH ST N STE A
SAINT PETERSBURG, FL 33716
CLIA ID# 10D2158976 (CAP)

SANCTION: Revocation of Accreditation

EFFECTIVE DATE: 6/17/2020

REASON: Laboratory Performance Does Not Meet CAP Standards of Accreditation

STATUS: As of 06/17/2020, Not Accredited by CAP
SREEKANTH REDDY, DIRECTOR
NORTHSIDE/ACC-TOWER
5670 PEACHTREE DUNWOODY RD, SUITE 110O
ATLANTA, GA 30342
CLIA ID# 11D0260593 (COLA)

SANCTION: Cease Testing for White Blood Cell Differential (WBC Diff)
EFFECTIVE DATE: 11/24/2020
REASON: Non-Compliance Due to Unsuccessful Participation in Proficiency Testing
STATUS: As of 12/31/2020 Cease Testing Still in Effect

HARRY LATHAM, DIRECTOR
CRISP REGIONAL HOSPITAL
902 SEVENTH STREET NORTH
CORDELE, GA 31015
CLIA ID# 11D0646027 (CAP)

SANCTION: Revocation of Accreditation
EFFECTIVE DATE: 2/11/2020
REASON: Laboratory Performance Does Not Meet CAP Standards of Accreditation
STATUS: As of 02/11/2020, Not Accredited by CAP

CHRIS Kligora, DIRECTOR
POLK MEDICAL CENTER
2360 ROCKMART HWY
CEDARTOWN, GA 30125
CLIA ID# 11D0670518 (TJC)

SANCTION: Cease Testing for Compatibility Testing
EFFECTIVE DATE: 10/02/2020
REASON: Non-Compliance Due to Unsuccessful Participation in Proficiency Testing
STATUS: As of 12/31/20 Cease Testing still in effect
CAROL EISENHUT, DIRECTOR
SEVEN HILLS OB-GYN ASSOCIATES LLC
11405 NORTH PENN ST, STE 260, Carmel, IN 46032
CLIA ID# 15D0353155 (COLA)

SANCTION: Cease Testing for Sodium
EFFECTIVE DATE: 04/08/2020
REASON: Non-Compliance Due to Unsuccessful Participation in Proficiency Testing
STATUS: As of 12/31/2020 Cease Testing Still in Effect

KELLY BROWN, DIRECTOR
JEFFERSONVILLE PEDIATRICS
207 SPARKS AVE STE 403
JEFFERSONVILLE, IN 47130
CLIA ID# 15D0359310

SANCTION: Cease Testing for Hematocrit (HCT)
EFFECTIVE DATE: 06/04/2020
REASON: Non-Compliance Due to Unsuccessful Participation in Proficiency Testing
STATUS: Test was Reinstated on 12/04/2020

DAVID STAPP, DIRECTOR
BAPTIST HEALTH FLOYD
1850 STATE ST
NEW ALBANY, IN 47150
CLIA ID# 15D0667167 (ACHC-HFAP)

SANCTION: Cease Testing for Urea Nitrogen
EFFECTIVE DATE: 5/22/2020
REASON: Non-Compliance Due to Unsuccessful Participation in Proficiency Testing
STATUS: As of 10/15/2020 Testing was resumed
SHERRIE WHITE, DIRECTOR  
SELLERSBURG HEALTHCARE CENTER  
7823 OLD SR 60  
SELLERSBURG, IN 47172  
CLIA ID# 15D0955783 (COLA)

SANCTION: Cease Testing for PO2  
EFFECTIVE DATE: 07/09/2020  
REASON: Non-Compliance Due to Unsuccessful Participation in Proficiency Testing  
STATUS: As of 12/31/2020 Cease Testing Still in Effect

BEN THOMPSON, DIRECTOR  
LAKE CHARLES MEMORIAL PULMONARY MEDICINE ABG LAB  
1701 OAK PARK BLVD  
LAKE CHARLES, LA 70601  
CLIA ID# 19D0864944 (CAP)

SANCTION: Cease Testing for Hematocrit  
EFFECTIVE DATE: 4/1/2020  
REASON: Non-Compliance Due to Unsuccessful Performance in Proficiency Testing  
STATUS: As of 12/31/2020 Cease Testing Still in Effect

VICKI STEEN, DIRECTOR  
WOMENS HEALTH & WELLNESS, LLC/SCOTT P STRIPLIN, MD  
77 STARBRUSH CIRCLE  
COVINGTON, LA 70433  
CLIA ID# 19D0989149 (COLA)

SANCTION: Cease Testing for Bacteriology  
EFFECTIVE DATE: 12/14/2020  
REASON: Non-Compliance Due to Unsuccessful Participation in Proficiency Testing  
STATUS: As of 12/31/2020 Cease Testing Still in Effect
RATISH GAMBHIRA, DIRECTOR
STONE CLINICAL LABORATORIES, LLC
615 BARONNE ST, STE 100
NEW ORLEANS, LA 70113
CLIA ID# 19D2108253 (CAP)

SANCTION: Probation
EFFECTIVE DATE: 8/26/2020
REASON: Quality and Severity of Deficiencies Is Significant Enough to Question Ability to Sustain Corrections; Corrective Action Fails to Support Implementation and Prevention of Recurrence in One or More Areas of the Laboratory
STATUS: As of 12/31/2020 Probation Still in Effect

TAMMIEY NAAB, DIRECTOR
BIOCERNA LLC
8161 MAPLE LAWN BLVD SUITE 375
FULTON, MD 20759
CLIA ID# 21D2059950 (CAP)

SANCTION: Cease Testing for Alpha-1-Antitrypsin
EFFECTIVE DATE: 6/1/2020
REASON: Non-Compliance Due to Unsuccessful Performance in Proficiency Testing
STATUS: As of 12/31/2020, Cease Testing Still in Effect

PRITI PATEL, DIRECTOR
INTERNAL MEDICINE & PREVENTIVE CARE PC
233 WINTHROP STREET
TAUNTON, MA 02780
CLIA ID# 22D1030094 (COLA)

SANCTION: Denial of Accreditation
EFFECTIVE DATE: 03/24/2020
REASON: Failure to Comply with Reasonable Request of COLA
STATUS: No Longer Accredited by COLA
<table>
<thead>
<tr>
<th>Institution</th>
<th>Director Name</th>
<th>Location</th>
<th>CLIA ID#</th>
<th>Sanction Description</th>
<th>Effective Date</th>
<th>Reason</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>VHS Children's Hospital of Michigan</td>
<td>Janet Poulak</td>
<td>3901 Beaubien Street, Detroit, MI 48201</td>
<td>23D0036460 (CAP)</td>
<td>Cease Testing for Hemoglobin</td>
<td>12/1/2020</td>
<td>Non-Compliance Due to Unsuccessful Performance in Proficiency Testing</td>
<td>As of 12/31/2020 Cease Testing Still in Effect</td>
</tr>
<tr>
<td>DLP Marquette General Hospital</td>
<td>Martin Matthews</td>
<td>850 W Baraga Avenue, Marquette, MI 49855</td>
<td>23D0038098 (TJC)</td>
<td>Cease Testing for Parasitology</td>
<td>12/2/2020</td>
<td>Non-Compliance Due to Unsuccessful Performance in Proficiency Testing</td>
<td>As of 12/31/2020 Cease Testing Still in Effect</td>
</tr>
<tr>
<td>Forest Health Medical Center</td>
<td>Shih Hon Li</td>
<td>135 South Prospect Street, Ypsilanti, MI 48198</td>
<td>23D0369390 (TJC)</td>
<td>Cease Testing for Total Protein</td>
<td>06/23/2020</td>
<td>Non-Compliance Due to Unsuccessful Participation in Proficiency Testing</td>
<td>Testing Reinstated Effective 12/04/2020</td>
</tr>
</tbody>
</table>
R. DAVID DEXTER, DIRECTOR
FAIRVIEW NORTHLAND REGIONAL HLTH CARE
911 NORTHLAND DRIVE
PRINCETON, MN 55371 CLIA ID# 24D0400744 (CAP)

SANCTION: Cease Testing for Ethanol
EFFECTIVE DATE: 2/21/2020
REASON: Non-Compliance Due to Unsuccessful Performance in Proficiency Testing
STATUS: Allowed to Resume Testing on 09/03/2020

BRIAN KAY, DIRECTOR
ST CLOUD HOSPITAL DECENTRALIZED LAB
1406 SIXTH AVE NORTH
SAINT CLOUD, MN 56303
CLIA ID# 24D0651612 (TJC)

SANCTION: Voluntary Cease Testing for Prothrombin Time
EFFECTIVE DATE: 08/04/2020
REASON: Non-Compliance Due to Unsuccessful Participation in Proficiency Testing
STATUS: As of 12/31/2020 Cease Testing Still in Effect

TRUDIE MUIR, DIRECTOR
FRANCES MAHON DEACONESS HOSPITAL
621 3RD STREET SOUTH
GLASGOW, MT 59230
CLIA ID# 27D0409794 (COLA)

SANCTION: Cease Testing for PCO2
EFFECTIVE DATE: 11/24/2020
REASON: Non-Compliance Due to Unsuccessful Participation in Proficiency Testing
STATUS: As of 12/31/2020 Cease Testing Still in Effect
Cease Testing for Lactate Dehydrogenase (LDH)  
12/14/2020 
Non-Compliance Due to Unsuccessful Participation in Proficiency Testing 
As of 12/31/2020 Cease Testing Still in Effect

Cease Testing for Compatibility Testing  
10/14/2020 
Non-Compliance Due to Unsuccessful Participation in Proficiency Testing 
As of 12/31/20 Cease Testing still in effect

Denial of Accreditation  
11/18/2020 
Failure to Adhere to COLA-Imposed Required Improvements 
No Longer Accredited by COLA

RICHARD BLAU, DIRECTOR  
RICHARD H BLAU MD-ARTHRITIS INSTITUTE  
120 BETHPAGE ROAD  
HICKSVILLE, NY 11801  
CLIA ID# 33D0155403 (COLA)

SANCTION: Cease Testing for Immunoglobulins IgE (IgE, Total)  
EFFECTIVE DATE: 09/28/2020  
REASON: Non-Compliance Due to Unsuccessful Participation in Proficiency Testing  
STATUS: As of 12/31/2020 Cease Testing Still in Effect

RICHARD GOLD, DIRECTOR  
SMITHTOWN MEDICAL SPECIALISTS PC  
215 EAST MAIN STREET  
SMITHTOWN, NY 11787  
CLIA ID# 33D0663082 (COLA)

SANCTION: Cease Testing for Sodium  
EFFECTIVE DATE: 04/08/2020  
REASON: Non-Compliance Due to Unsuccessful Participation in Proficiency Testing  
STATUS: As of 12/31/2020 Cease Testing Still in Effect

ARNOLD WEG, DIRECTOR  
ARNOLD WEG MD  
710 PARK AVENUE, SUITE 1C  
NEW YORK, NY 10021  
CLIA ID# 33D0887555 (COLA)

SANCTION: Cease Testing for Thyroid Stimulating Hormone (TSH), HDL Cholesterol, Chloride, Thyroxine (T4), Triiodothyronine (T3)  
EFFECTIVE DATE: 02/13/2020  
REASON: Non-Compliance Due to Unsuccessful Participation in Proficiency Testing  
STATUS: As of 12/31/2020 Cease Testing Still in Effect
<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
<th>CLIA ID #</th>
<th>(COLA)</th>
<th>SANCTION</th>
<th>EFFECTIVE DATE</th>
<th>REASON</th>
<th>STATUS</th>
</tr>
</thead>
<tbody>
<tr>
<td>STEVEN SIEGEL</td>
<td>58TH STREET MEDICAL PLLC</td>
<td>33D1050671</td>
<td>(COLA)</td>
<td>Denial of Accreditation</td>
<td>03/04/2020</td>
<td>Failure to Adhere to COLA-Imposed Required Improvements</td>
<td>No Longer Accredited by COLA</td>
</tr>
<tr>
<td>LEWIS ROSENBERG</td>
<td>CONTEMPORARY OB-GYN HEALTHCARE ASSOCIATES OF LI PC</td>
<td>33D1095249</td>
<td>(COLA)</td>
<td>Denial of Accreditation</td>
<td>01/29/2020</td>
<td>Failure to Comply with Reasonable Request of COLA</td>
<td>No Longer Accredited by COLA</td>
</tr>
<tr>
<td>RICHARD PIPPIN</td>
<td>PHYSICIANS EAST-FARMVILLE</td>
<td>34D0241889</td>
<td>(COLA)</td>
<td>Cease Testing for Bacteriology</td>
<td>03/11/2020</td>
<td>Non-Compliance Due to Unsuccessful Participation in Proficiency Testing</td>
<td>On 03/18/2020 Tests was Deleted from Menu</td>
</tr>
</tbody>
</table>
GARY HECK, DIRECTOR
PHYSICIANS EAST - KINSTON
744 AIRPORT ROAD
KINSTON, NC 28504
CLIA ID# 34D0246185 (COLA)

SANCTION: Cease Testing for Bacteriology
EFFECTIVE DATE: 03/10/2020
REASON: Non-Compliance Due to Unsuccessful Participation in Proficiency Testing
STATUS: On 03/18/2020 Tests was Deleted from Menu

MARK WARREN, DIRECTOR
PHYSICIANS EAST, PA
ATTN BECKY OAKES - DIR CLINICAL & ANCILLARY SVCS
GREENVILLE, NC 27834
CLIA ID# 34D0655224 (COLA)

SANCTION: Cease Testing for Albumin
EFFECTIVE DATE: 04/08/2020
REASON: Non-Compliance Due to Unsuccessful Participation in Proficiency Testing
STATUS: As of 12/31/2020 Cease Testing Still in Effect

PATRICK MORGANTE, DIRECTOR
SEA BREEZE FAMILY PRACTICE, PA
3004 BRIDGES STREET
MOREHEAD CITY, NC 28557
CLIA ID# 34D0954643 (COLA)

SANCTION: Cease Testing for White Blood Cell Differential (WBC Diff)
EFFECTIVE DATE: 09/30/2020
REASON: Non-Compliance Due to Unsuccessful Participation in Proficiency Testing
STATUS: As of 12/31/2020 Cease Testing Still in Effect
DAVID ECKERT, DIRECTOR
PERSONALIZED HEMATOLOGY ONCOLOGY OF
WAKE FOREST, PLLC
11635 NORTH PARK DRIVE, SUITE 250
WAKE FOREST, NC 27587
CLIA ID# 34D2043480 (COLA)

SANCTION: Cease Testing for White Blood Cell Differential (WBC Diff)
EFFECTIVE DATE: 09/30/2020
REASON: Non-Compliance Due to Unsuccessful Participation in Proficiency Testing
STATUS: As of 12/31/2020 Cease Testing Still in Effect

SANJIV PRABHU, DIRECTOR
METAMARK GENETICS, INC
1912 TW ALEXANDER DRIVE, ROOMS 243 & 250
DURHAM, NC 27709
CLIA ID# 34D2130056 (CAP)

SANCTION: Probation
EFFECTIVE DATE: 4/22/2020
REASON: Quality and Severity of Deficiencies Is Significant Enough to Question Ability to Sustain Corrections; Corrective Action Fails to Support Implementation and Prevention of Recurrence in One or More Areas of the Laboratory
STATUS: Withdrew from CAP accreditation program on 7/10/2020 prior to removal of probation

JOSEPH SREENAN, DIRECTOR
WYANDOT MEMORIAL HOSPITAL
885 NORTH SANDUSKY AVENUE
UPPER SANDUSKY, OH 43351
CLIA ID# 36D0330837 (ACHC-HFAP)

SANCTION: Cease Testing for pCO2
EFFECTIVE DATE: 9/28/2020
REASON: Non-Compliance Due to Unsuccessful Participation in Proficiency Testing
STATUS: As of 11/20/2020 Testing was resumed
CARL WEHRI, DIRECTOR
DELPHOS FAMILY PHYSICIANS INC
1775 E FIFTH ST
DELPHOS, OH 45833
CLIA ID# 36D0666777 (COLA)

SANCTION: Cease Testing for Red Blood Cell Count (Erythrocyte Count (RBC
EFFECTIVE DATE: 01/15/2020
REASON: Non-Compliance Due to Unsuccessful Participation in Proficiency Testing
STATUS: Withdrew 2/6/2020 Prior to Reinstatement. No Longer Accredited by COLA

RUCHI SACHDEV, DIRECTOR
ALLIANCEHEALTH DURANT
DURANT HMA, LLC
1800 UNIVERSITY BOULEVARD
DURANT, OK 74701
CLIA ID# 37D0656767 (TJC)

SANCTION: Cease Testing for pO2
EFFECTIVE DATE: 08/10/20
REASON: Non-Compliance Due to Unsuccessful Participation in Proficiency Testing
STATUS: As of 12/31/20 Cease Testing still in effect

CHITRA KOHLI, DIRECTOR
MCI DIAGNOSTIC CENTER, LLC
7024 S UTICA AVE TULSA, OK 74136
CLIA ID# 37D2011460 (CAP)

SANCTION: Cease Testing for Complement C3
EFFECTIVE DATE: 1/4/2020
REASON: Non-Compliance Due to Unsuccessful Participation in Proficiency Testing
STATUS: Allowed to Resume Testing on 11/17/2020
SHERRITA WILSON, DIRECTOR
MCI DIAGNOSTIC CENTER, LLC
7024 S UTICA AVE TULSA, OK 74136
CLIA ID# 37D2011460 (COLA)

SANCTION: Cease Testing for Alpha-Fetoprotein - Tumor Marker, Complement C3, Complement C4, Immunoglobulins IgA, Immunoglobulins IgG, Immunoglobulins IgM
EFFECTIVE DATE: 01/29/2020
REASON: Non-Compliance Due to Unsuccessful Performance in Proficiency Testing
STATUS: Test was Reinstated on 11/15/2020

SHUAIB OKPONOBI, DIRECTOR
GROVE CITY MEDICAL CENTER
631 N BROAD ST EXT
GROVE CITY, PA 16127
CLIA ID# 39D0657188 (ACHC-HFAP)

SANCTION: Cease Testing for Digoxin
EFFECTIVE DATE: 07/08/2020
REASON: Non-Compliance Due to Unsuccessful Participation in Proficiency Testing
STATUS: As of 10/21/2020 Testing was resumed

STEVEN VALLY, DIRECTOR
GEORGETOWN MEMORIAL HOSPITAL
606 BLACK RIVER RD
GEORGETOWN, SC 29440
CLIA ID# 42D0251058 (TJC)

SANCTION: Cease Testing for pO2
EFFECTIVE DATE: 11/10/2020
REASON: Non-Compliance Due to Unsuccessful Participation in Proficiency Testing
STATUS: As of 12/31/20 Cease Testing still in effect
DONALD FREDERICK, DIRECTOR
LAGNIAPPE MEDICAL CLINICS, LLC
74 POLO ROAD
COLUMBIA, SC 29223
CLIA ID# 42D2126927 (COLA)

SANCTION: Cease Testing for Hematocrit (HCT)
EFFECTIVE DATE: 06/04/2020
REASON: Non-Compliance Due to Unsuccessful Participation in Proficiency Testing
STATUS: On 06/23/2020 Tests was Deleted from Menu

PATRICK LOLLIS, DIRECTOR
FAMILY PRACTICE ASSOCS OF EASLEY, PA
700 BRUSHY CREEK RD
EASLEY, SC 29642
CLIA ID# 42D0252906

SANCTION: Cease Testing for White Blood Cell Differential (WBC Diff)
EFFECTIVE DATE: 01/15/2020
REASON: Non-Compliance Due to Unsuccessful Participation in Proficiency Testing
STATUS: Denied 01/29/2020 Prior to Reinstatement.
No Longer Accredited by COLA

PATRICK LOLLIS, DIRECTOR
FAMILY PRACTICE ASSOCS OF EASLEY, PA
700 BRUSHY CREEK RD
EASLEY, SC 29642
CLIA ID# 42D0252906 (COLA)

SANCTION: Denial of Accreditation
EFFECTIVE DATE: 01/29/2020
REASON: Failure to Comply with Reasonable Request of COLA
STATUS: No Longer Accredited by COLA
SANCTION: Probation
EFFECTIVE DATE: 3/25/2020
REASON: Quality and Severity of Deficiencies Is Significant Enough to Question Ability to Sustain Corrections; Corrective Action Fails to Support Implementation and Prevention of Recurrence in One or More Areas of the Laboratory
STATUS: As of 12/31/2020 Probation Still in Effect

SANCTION: Cease Testing for Activated Partial Thromboplastin Time (APTT)
EFFECTIVE DATE: 02/13/2020
REASON: Non-Compliance Due to Unsuccessful Participation in Proficiency Testing
STATUS: Test was Reinstated on 10/14/2020

SANCTION: Cease Testing for White Blood Cell Differential (WBC Diff)
EFFECTIVE DATE: 05/08/2020
REASON: Non-Compliance Due to Unsuccessful Participation in Proficiency Testing
STATUS: On 05/15/2020 Test was Deleted from Menu
ANGELA LAPUS, DIRECTOR
CAHRMC, LLC
DBA RICE MEDICAL CENTER
600 S AUSTIN ROAD
EAGLE LAKE, TX 77434
CLIA ID# 45D0495496 (COLA)

SANCTION: Cease Testing for Chloride
EFFECTIVE DATE: 07/24/2020
REASON: Non-Compliance Due to Unsuccessful Participation in Proficiency Testing
STATUS: As of 12/31/2020 Cease Testing Still in Effect

GEETA PARANJAPE, DIRECTOR
COASTAL BEND BLOOD CENTER
209 NORTH PADRE ISLAND CENTER
CORPUS CHRISTI, TX 78406
CLIA ID# 45D0503125 (AABB)

SANCTION: Cease testing for eluate
EFFECTIVE DATE: 5/11/2020
REASON: Non-Compliance Due to Unsuccessful Performance in Proficiency Testing
Laboratory voluntarily Ceased Testing
AABB notified on 5/22/2020

CLIFFORD SAULS, DIRECTOR
CHCA WOMAN’S HOSPITAL, LP
DBA THE WOMAN’S HOSPITAL OF TEXAS
7600 FANNIN STREET
HOUSTON, TX 77054
CLIA ID# 45D0660158 (CAP)

SANCTION: Cease Testing for T3 (Triiodothyronine)
EFFECTIVE DATE: 7/10/2020
REASON: Non-Compliance Due to Unsuccessful Performance in Proficiency Testing
STATUS: As of 12/31/2020, Cease Testing Still in Effect
DAVID STANLEY, DIRECTOR
HENDRICK REGIONAL LABORATORIES
1900 PINE STREET
ABILENE, TX 79601
CLIA ID# 45D0663748 (CAP)

SANCTION: Cease Testing for hCG, Serum
EFFECTIVE DATE: 6/6/2020
REASON: Non-Compliance Due to Unsuccessful Performance in Proficiency Testing
STATUS: Allowed to Resume Testing on 12/17/2020

DAVID PRIER, DIRECTOR
HUNTSVILLE PEDIATRIC & ADULT MEDICINE ASSOC
100 MEDICAL CENTER PARKWAY SUITE 1000
HUNTSVILLE, TX 77340
CLIA ID# 45D0721321 (COLA)

SANCTION: Cease Testing for Hematocrit (HCT)
EFFECTIVE DATE: 07/24/2020
REASON: Non-Compliance Due to Unsuccessful Participation in Proficiency Testing
STATUS: On 07/29/2020 Test was Deleted from Menu

JEFFREY CHRISTAL, DIRECTOR
METHODIST TEXSAN HOSPITAL
A METHODIST HOSPITAL FACILITY
6700 I-H 10 WEST
SAN ANTONIO, TX 78201
CLIA ID# 45D1018034 (CAP)

SANCTION: Cease Testing for Compatibility Testing
EFFECTIVE DATE: 5/4/2020
REASON: Non-Compliance Due to Unsuccessful Performance in Proficiency Testing
STATUS: As of 12/31/2020, Cease Testing Still in Effect
Cease Testing for Protein, Total

EFFECTIVE DATE: 04/08/2020

REASON: Non-Compliance Due to Unsuccessful Participation in Proficiency Testing

STATUS: As of 12/31/2020 Cease Testing Still in Effect

Cease Testing for Creatine

EFFECTIVE DATE: 11/24/2020

REASON: Non-Compliance Due to Unsuccessful Participation in Proficiency Testing

STATUS: As of 12/31/2020 Cease Testing Still in Effect


EFFECTIVE DATE: 03/06/2020

REASON: Non-Compliance Due to Unsuccessful Participation in Proficiency Testing

STATUS: Tests were Reinstated on 09/10/2020
Cease Testing for pO2
2/21/2020
Non-Compliance Due to Unsuccessful Performance in Proficiency Testing
Allowed to Resume Testing on 06/11/2020

Cease Testing for Triglyceride
11/24/2020
Non-Compliance Due to Unsuccessful Participation in Proficiency Testing
On 12/07/2020 Test was Deleted from Menu

Cease Testing for White Blood Cell Differential (WBC Diff)
01/15/2020
Non-Compliance Due to Unsuccessful Participation in Proficiency Testing
Withdrew 2/28/20 Prior to Reinstatement.
No Longer Accredited by COLA
AZIM KARIM, DIRECTOR GREATER TEXAN HEALTH LLC
10021 SOUTH MAIN STREET SUITE B-2
HOUSTON, TX 77025
CLIA ID# 45D2130481 (COLA)

SANCTION: Cease Testing for Thyroid Stimulating Hormone (TSH), Thyroxine, Free (FT4)
EFFECTIVE DATE: 07/08/2020
REASON: Non-Compliance Due to Unsuccessful Participation in Proficiency Testing
STATUS: As of 12/31/2020 Cease Testing Still in Effect

JOHN MASCIALE, DIRECTOR
SOUTH TEXAS BONE AND JOINT
601 TEXAN TRAIL
CORPUS CHRISTI, TX 78411 CLIA ID# 45D2160860 (COLA)

SANCTION: Cease Testing for Protein, Total
EFFECTIVE DATE: 07/24/2020
REASON: Non-Compliance Due to Unsuccessful Participation in Proficiency Testing
STATUS: As of 12/31/2020 Cease Testing Still in Effect

PATRICIA KANDALAFT, DIRECTOR
TCL-GRANDRIDGE
7131 WEST GRANDRIDGE BLVD
KENNEWICK, WA 99336
CLIA ID# 50D0639835 (CAP)

SANCTION: Probation
EFFECTIVE DATE: 1/22/2020
REASON: Quality and Severity of Deficiencies Is Significant Enough to Question Ability to Sustain Corrections; Corrective Action Fails to Support Implementation and Prevention of Recurrence in One or More Areas of the Laboratory
STATUS: As of 12/31/2020 Probation Still in Effect
BRAD ANDERSEN, DIRECTOR SFH DIAGNOSTICS
22180 OLYMPIC COLLEGE WAY NW STE 201
POULSBO, WA 98370
CLIA ID# 50D2024139 (COLA)

SANCTION: Cease Testing for White Blood Cell Differential (WBC Diff)
EFFECTIVE DATE: 04/17/2020
REASON: Non-Compliance Due to Unsuccessful Participation in Proficiency Testing
STATUS: Test was Reinstated on 12/16/2020

MARY TAYLOR, DIRECTOR
ROANE GENERAL HOSPITAL
200 HOSPITAL DRIVE
SPENCER, WV 25276
CLIA ID# 51D0234035 (COLA)

SANCTION: Cease Testing for Sodium
EFFECTIVE DATE: 07/24/2020
REASON: Non-Compliance Due to Unsuccessful Participation in Proficiency Testing
STATUS: As of 12/31/2020 Cease Testing Still in Effect

TIMOTHY WEILAND, DIRECTOR
MARSHFIELD LABS- EAU CLAIRE/
MARSHFIELD MEDICAL CENTER- EAU CLAIRE
2116 CRAIG RD SUITE 200 AND 300
EAU CLAIRE, WI 54701
CLIA ID# 52D0396600 (COLA)

SANCTION: Cease Testing for Fibrinogen
EFFECTIVE DATE: 02/10/2020
REASON: Non-Compliance Due to Unsuccessful Participation in Proficiency Testing
STATUS: Withdrew 2/13/20 Prior to Reinstatement.
No Longer Accredited by 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

Albert Cohen, M.D.
No CLIA number

DECISION NUMBER: CR5616
DECISION DATE: May 21, 2020
DECISION: FOR CMS

Kensington Diagnostics LLC
05D2087480

DECISION NUMBER: DAB 2992
DECISION DATE: March 16, 2020
DECISION: FOR CMS

Calvin S. Rosenfeld, M.D., P.A.
10D0277889

DECISION NUMBER: CR5736
DECISION DATE: October 16, 2020
DECISION: FOR CMS

Charles S. Pewitt, D.O., d/b/a Jackson Medical Center
26D0969305

DECISION NUMBER: ALJ Ruling No. 2020-6
DECISION DATE: February 14, 2020
DECISION: FOR CMS

Charles S. Pewitt, D.O., d/b/a Jackson Medical Center
26D0969305

DECISION NUMBER: 3009
DECISION DATE: July 31, 2020
DECISION: FOR CMS

Gamma Healthcare, Inc
26D1041510, 26D2102945

Case No. 6:20-CV-033337-MDH
DECISION DATE: October 28, 2020
DECISION: FOR CMS
RED Laboratories
29D2019771

DECISION NUMBER: CR5723
DECISION DATE: September 29, 2020
DECISION: FOR CMS

Laboratory Corporation of America Holdings, Inc.
34D0655205

DECISION NUMBER: CR5523
DECISION DATE: January 21, 2020
DECISION: FOR CMS

Laboratorio Concordia Lugaro
40D0658188

DECISION NUMBER: CR5589
DECISION DATE: April 16, 2020
DECISION: FOR CMS
7. A LIST OF LABORATORIES AGAINST WHICH CMS HAS BROUGHT SUIT UNDER SECTION 493.1846 AND THE REASON FOR THOSE ACTIONS.

*** NO DATA FOUND ***
8. A LIST OF LABORATORIES THAT HAVE BEEN EXCLUDED FROM PARTICIPATION IN MEDICARE OR MEDICAID AND THE REASON FOR EXCLUSION.

MARTIAL KNIESER, DIRECTOR
KLARITY MEDICAL LABORATORY
7330 E 82ND ST, STE C
INDIANAPOLIS, IN 46256
CLIA ID# 15D2105460

JAMSHED HAQ, DIRECTOR
TENNESSEE VALLEY REGIONAL LABORATORY
DBA SPRINGS MEDICAL LAB
7349 MIDDLEBROOK PIKE
KNOXVILLE, TN 37909
CLIA ID# 44D2062571
9. CORRECTION OF ANY ERRONEOUS STATEMENTS OF INFORMATION THAT APPEARED IN THE 2019 REGISTRY.

KEVIN ROSENBLATT, DIRECTOR
VYBREM LABS
CLIA ID# 04D2132998

Correction: Kevin Rosenblatt, Director was not included in the sanctions taken against this laboratory.

SANJOY BANERJEE, DIRECTOR
KENSINGTON DIAGNOSTICS LLC
CLIA ID# 05D2087480

Correction: Principal Sanctions did not appear on the 2019 Registry

SANCTION: Cancel Medicare/Medicaid Approval
Revocation of CLIA Certificate

EFFECTIVE DATE: 08/05/2019

REASON: Condition Level Non-Compliance with IJ
Failure to Submit Acceptable POC or AOC
2 Year Prohibition-Owning, Operating and Directing

STATUS: Appeal Filed By Laboratory
Hearing Decision Sustained CMS Sanc Detem

SANJOY BANERJEE, DIRECTOR
KENSINGTON DIAGNOSTICS LLC
CLIA ID# 05D2087480

Correction: Alternative Sanctions did not appear on the 2019 Registry

SANCTION: Civil Money Penalty
Directed Portion Plan of Correction (DPOC)

EFFECTIVE DATE: 08/05/2019

REASON: Condition Level Non-Compliance with IJ
Failure to Submit Acceptable POC or AOC
2 Year Prohibition-Owning, Operating and Directing

STATUS: Appeal Filed By Laboratory
Hearing Decision Sustained CMS Sanc Detem
Correction: Principal Sanction did not appear on the 2019 Registry

SANCTION: Revocation of CLIA Certificate

EFFECTIVE DATE: 11/26/2019

REASON: Condition Level Non-Compliance with IJ
Failure to Submit Acceptable POC or AOC
2 Year Prohibition-Owning, Operating and Directing

STATUS: Appeal Filed By Laboratory
Hearing Decision Sustained CMS Sanc Detem
10. OTHER ACTIONS. THIS SECTION INCLUDES OTHER SPECIFIC INFORMATION THAT MAY BE USEFUL IN EVALUATING THE PERFORMANCE OF LABORATORIES AS SPECIFIED IN 493 CFR 1850(a). IT ALSO INCLUDES INFORMATION PROVIDED BY CLIA EXEMPT STATES.

*** NO DATA FOUND ***