

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0506643	(X3) Date Survey Completed 09/22/2021
Name of Provider or Supplier Regence Health Network, Inc	Street Address, City, State 125 West Park Ave, Hereford, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Review of manufacturer's instructions, patient final reports, personnel records and interview of facility personnel found the laboratory failed to follow the manufacturer's instructions when using the Sofia SARS Antigen FIA test kits for testing patients as defined by the manufacturer under the Emergency Use Authorization (EUA). The findings included: 1. Review of the manufacturer's instructions for the Sofia SARS Antigen FIA found on page 19 under the heading CONDITIONS OF AUTHORIZATION FOR LABORATORY " Authorized laboratories using the Sofia SARS Antigen FIA must include with the test result reports, all authorized Fact Sheets." Further review found: " all operators using your product must be appropriately trained in performing and interpreting the results of your product, use appropriate personal protective equipment when handling this kit, and use your product in accordance with authorized labeling." 2. Review of patient results found no fact sheets included with the final report for three of three patient reports reviewed. 3. Review of personnel records found no documentation of training for five of five testing personnel. Interview of Testing person one on the CMS Laboratory Personnel Report conducted September 22, 2021 at 10:02 AM confirmed that the Fact Sheets were not included with the patient test results for SARS COV-2 testing, and the laboratory failed to document training for five of five testing personnel.</p>
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p>

Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's CBC QC records from 11/1/2020 to 9/22/21 and confirmed in an interview the laboratory failed to retain 6 of 7 assay sheets for QC lots of Horiba Minotrol-16 Hematology Reference Control for a minimum of 2 years. The findings were: 1. Review of the laboratory QC records found the laboratory failed to retain assay sheets for 6 of 7 quality control lots used between 11/1/20 and 9/22/21. MX430 Exp: 2021-09-05 MX429 Exp: 2021-07-05 MX428 Exp: 2021-05-05 MX427 Exp: 2021-03-05 MX426 Exp: 2021-01-05 MX425 Exp: 2020-11-05 2. An interview with the lab coordinator on 9/23/21 at 9:35 PM in the conference room confirmed the laboratory discarded the previous CBC QC lot assay sheets when new CBC QC lot put in use. Key: CBC=Complete Blood Count QC=Quality Control

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE

CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's verification records, the laboratory's procedures, CMS 116 application, and confirmed in an interview the laboratory failed to verify four of four required performance specifications, accuracy, precision, reportable ranges, and reference range, for the Horiba ABX Micro 60 hematology analyzer. The findings were: 1. Review of the laboratory's verification records for Horiba ABX Micros 60 (SN# 904CS98713) revealed the laboratory did not verify the performance specifications for: Accuracy Precision Reportable Ranges Normal values (Reference Range) 2. Review of the CMS 116 application signed by the CEO on 09/13/21 revealed the CBC annual volume was 3,600. 3. An interview with the lab coordinator on 9/22/21 at 10:00 am in the break room confirmed the above performance specifications were not verified. Key: CMS=Center of Medicare and Medicaid Service CEO=Chief executive officer CBC=Complete Blood Count

D5783

CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(2)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:
 Based on review of the laboratory's procedures, the laboratory's CBC QC records from 2020-2021, CMS 116 application, and confirmed in an interview the laboratory failed to document corrective actions when Hemoglobin (HGB) quality control results failed to meet the manufacturers's acceptable ranges for 10 of 50 days reviewed on Horiba ABX Micros 60 hematology analyzer. The findings were: 1. Review of the laboratory's procedures revealed no policy written policy for documenting corrective actions when QC results failed to meet acceptable ranges. 2. Random review the laboratory's CBC QC records from 2020-2021 on Horiba ABX Micros 60 hematology analyzer revealed 10 of 50 days reviewed when the HGB QC failed to meet the manufacturer's acceptable ranges without corrective actions documented. (L=Low, N=Normal, H=High) 9/20/21 Hgb 6.6 QC Lot#: MX431L Exp: 2021-11-05 Ranges: 5.6-6.4 9/8/21 Hgb 5.0 QC Lot#: MX431L Exp: 2021-11-05 Ranges: 5.6-6.4 9/8/21 Hgb 13.0 QC Lot#: MX431N Exp: 2021-11-05 Ranges: 13.1-14.3 9/3/21 Hgb 19.5 QC Lot#: MX431H Exp: 2021-11-05 Ranges: 17.7-19.1 8/23/21 Hgb 12.6 QC Lot#: MX430N Exp: 2021-09-05 Ranges: 13.1-14.3 8/16/21 Hgb 4.5 QC Lot#: MX430L Exp: 2021-09-05 Ranges: 5.6-6.4 7/30/21 Hgb 19.1 QC Lot#: MX430H Exp: 2021-09-05 Ranges: 17.5-18.9 8/28/20 Hgb 5.2 QC Lot#: MX424L Exp: 2020-09-05 Ranges: 5.7-6.5 8/21/20 Hgb 6.1 QC Lot#: MX424H Exp: 2020-09-05 Ranges: 17.7-19.1 7/13/20 Hgb 12.6 QC Lot#: MX424N Exp: 2020-09-05 Ranges: 13.0-14.2 3. Review of CMS 116 application signed by the CEO on 09/13/21 revealed the CBC annual volume was 3,600. 4. An interview with the lab coordinator on 9/22/21 at 12:18 PM in the break room confirmed the laboratory did not always document corrective actions when results failed to meet the manufacturer's acceptable ranges. Key: CBC=Complete Blood Count QC=Quality Control HG=Hemoglobin CMS=Center of Medicare and Medicaid Service CEO=Chief executive officer Hgb=Hemoglobin

D5807

TEST REPORT
 CFR(s): 493.1291(d)

Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:
 Based on review of the manufacturer's user manual, patient final reports from 1/1/21 to 9/21/21, and confirmed in an interview the laboratory failed to provide verified normal ranges for five of five analytes reviewed, WBC, RBC, HGB, HCT, and PLT, tested on the Horiba ABX Micros 60 hematology analyzer. The findings were: 1. Review of Horiba ABX Micros 60 Hematology Analyzer User Manual (Ref: RAB 043MUS) for five analytes revealed under 3.6 Normal Ranges, "WBC ($10^3/mm^3$) Male 4.7-9.6 Female 4.9-12.3 RBC ($10^6/mm^3$) Male 4.37-5.63 Female 3.90-5.10 HGB (g/dL) Male 13.5-16.5 Female 12.0-15.0 HCT (%) Male 41-50 Female 37-45 PLT ($10^3/mm^3$) Male 145-355 Female 150-330" 2. Review of five patient final reports found reference ranges defined as: WBC 5.0-11.0 K/uL RBC 4.60-5.50 M/uL HGB 13.5-16.5 g/dL HCT 41.0-49.6 % PLT 150-400 $\times 10^3$ 3. Further review of five patient final reports revealed the laboratory did not include reference ranges specific to sex to be used by the individual interpreting the results. 1/14/21 Sex:M Specimen /Accession ID: 630763 3/9/21 Sex:M Specimen/Accession ID: 639812 9/8/21 Sex:F Specimen/Accession ID: 670084 9/20/21 Sex:F Specimen/Accession ID: 672322 9/21

/21 Sex:F Specimen/Accession ID: 672665 4. An interview with the lab coordinator on 9/22/21 at 2:57 PM in the break room confirmed the reference ranges were not verified when the new instrument installed. Key: WBC=White Blood Cell RBC=Red Blood Cell HGB=Hemoglobin HCT=Hematocrit PLT=Platelets

D6033

TECHNICAL CONSULTANT-MODERATE COMPEXITY
CFR(s): 493.1409

The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:
Review of the CMS Report 209 Laboratory Personnel Report, personnel records and interview of facility personnel found the laboratory failed to have a technical consultant to provide oversight of laboratory services that met the minimum education requirements. (see D 6035)

D6035

TECHNICAL CONSULTANT QUALIFICATIONS
CFR(s): 493.1411

(a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.

This STANDARD is not met as evidenced by:

Review of the CMS Report 209 Laboratory Personnel Report, personnel records and interview of facility personnel found the laboratory failed to have a technical consultant to provide oversight that met the minimum education requirements. The findings included: 1. Review of the CMS Report 209 Laboratory Personnel Report found one Technical Consultant identified. 2. Review of the personnel file for the Technical Consultant found he had earned the following degrees: Associate in Applied Science for Medical Laboratory Technology Bachelor of Business Administration Master of Business Administration Management 3. Interview of the director of Operations and Ancillary Services conducted September 22, 2021 at 10:42 confirmed the individual identified as the Technical Consultant of the laboratory had not earned at least a bachelor degree in a chemical, physical or biological science or medical technology, and had been " listed as the Technical Consultant of this lab under the previous accrediting agency since 1995 and has been in that position since".