Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0664603	09/23/2021
Name of Provider or Supplier	**Street Address, City, State**	
Regence Health Network Ross	3113 Ross Street, Amarillo, 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	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) 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. 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. "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 personnel records found no documentation of training for seven of seven testing personnel. 3. Interview of Testing person one on the CMS Laboratory Personnel Report conducted September 23, 2021 at 09:37AM confirmed the laboratory failed to document training for seven of seven testing personnel.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) 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 found that the laboratory failed to retain 6 of 7 QC lots of Horiba Minotrol-16 Hematology Reference Control assay sheets 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 am in the conference room confirmed the laboratory discarded the assay sheets for previous CBC QC lots when a new CBC QC lot put in use. Key: CBC=Complete Blood Count QC=Quality Control
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the laboratory's verification records, the laboratory's policy, and confirmed in an interview found the laboratory failed to have Horiba Micros 60 policy approved, signed and dated by the current LD for one of one Horiba ABX Micros 60 hematology analyzer, before use. The findings were: 1. Review of the laboratory's verificaiton records revealed the current CBC instrument, Horiba ABX Micros 60 hematology analyzer (SN# 904CS98707) was put in use in March, 2020. 2. Review of the laboratory's policy revealed the policy titled "Horiba Micros 60" had no documentation of being approved, signed and dated by the current LD for Horiba ABX Micros 60 hematology analyzer. 3. An interview with the lab coordinator on 9/23 /21 at 9:23 am in the breakroom confirmed the above findings. Key: LD=Laboratory Director CBC=Complete Blood Count
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 revealed the laboratory failed to verify four of four required performance specifications, accuracy, precision, reportable ranges, and reference range, on Horiba ABX Micro 60 hematology analyzer. The findings were: 1. Review of the laboratory's verification records for Horiba ABX Micros 60 (SN# 904CS98707) revealed the laboratory did not verify four performance specifications. Accuracy Precision Linearity (Reportable Range) Normal Range (Reference Range) 2. Review of CMS 116 application signed by the CEO on 9/13/21 revealed the CBC annual volume was 45,726. 3. An interview with

	the lab coordinator on 9/23/21 at 9:23 am in the conference 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
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the manufacturer's user manual, the laboratory's policy, and confirmed in an interview found the laboratory failed to establish CBC QC acceptability criteria for three of three QC materials on Horiba ABX Micros 60 Hematology Analyzer. The findings were: 1. Review of Horiba ABX Micros 60 Hematology Analyzer User Manual (Ref: RAB 043MUS) revealed under 2. Daily Quality Control & Calibration verification, "Before analyzing any patient blood samples, it is recommended that that Operator performs Quality Control analysis on 3 levels of Control Blood Material, (Low, Normal, and High), to verify that the ABX Micros 60 is performing within the specified ranges of the Quality control material." 2. Review of the laboratory's policy titled "Horiba Micros 60" revealed under Quality Control, "Analyze three levels of control material (low, normal, & high) per day of testing according to regulatory standards of performance." 3. Further review of the laboratory's policy titled "Horiba Micros 60" revealed no documentation of CBC QC acceptability criteria for Horiba ABX Micros 60 Hematology Analyzer (SN#904CS98707). 4. An interview with the lab coordinator on 9/23/21 at 11:00 am in the conference room confirmed the above findings. Key: CBC=Complete Blood Count QC=Quality Control RHN=Regence Health Network
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of manufacturer's CBC QC acceptable ranges, CBC QC records from 2020-2021, patient records, and confirmed in an interview found the laboratory failed to have two of three levels of QC testing materials to meet manufacturer's acceptable ranges for one of three analytes reviewed (RBC) before patient testing for 1 of 10

	days reviewed. The findings were: 1. Review of RBC QC on Lot#424 Exp: 2020-09-05 for Level Low, Normal, and High on 8/13/20 revealed the manufacturer's acceptable ranges were: L: 2.21-2.51 N: 4.38-4.74 H: 5.45-5.85 2. Review of RBC QC on Lot#424 Exp: 2020-09-05 for each level (L, N, H) on 8/13/20 revealed two of three RBC QCs did not meet the manufacturer's acceptable ranges between 7:47 am to 12:44 pm when the low control met the manufacturer's acceptable range at 12:45 pm. Low at 0747 am 2.18 (RBC range for Low: 2.21-2.51) at 1241 pm 2.19 (RBC range for Low: 2.21-2.51) High at 0751 am 5.38 (RBC range for High: 5.45-5.85) at 1243 pm 5.40 (RBC range for High: 5.45-5.85) at 1248 pm 5.40 (RBC range for High: 5.45-5.85) 3. Review of patient records revealed the laboratory tested 19 patients between 7:47am to 12:44 pm before two QCs met the manufacturer's acceptable ranges. 8/13/20 at 08:54 am Patient#: 161505 8/13/20 at 09:36 am Patient#: 223006 8/13/20 at 10:08 am Patient#: 189758 8/13/20 at 10:09 am Patient#: 170636 8/13/20 at 10:38 am Patient#: 106524 8/13/20 at 10:46 am Patient#: 223172 8/13/20 at 10:48 am Patient#: 130679 8/13/20 at 10:59 am Patient#: 113576 8/13/20 at 11:02 am Patient#: 323811 8/13/20 at 11:19 am Patient#: 337502 8/13/20 at 11:23 am Patient#: 261689 8/13/20 at 11:25 am Patient#: 189169 8/13/20 at 11:35 am Patient#: 219596 8/13/20 at 11:44 am Patient#: 343263 8/13/20 at 11:51 am Patient#: 128472 8/13/20 at 12:01 pm Patient#: 237250 8/13/20 at 12:21 pm Patient#: 117459 8/13/20 at 12:25 pm Patient#: 357595 8/13/20 at 12:35 pm Patient#: 352421 4. An interview with the lab coordinator on 9/23/21 at 11:40 am in the conference room confirmed the above findings. Key: CBC=Complete Blood Count QC=Quality Control RBC=Red Blood Cell L=Low N=Normal H=High
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 found the laboratory failed to document corrective actions when quality control results for Red Blood Cell (RBC) failed to meet the manufacturers's acceptable range 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 for QC out of acceptable ranges for CBC testing on Horiba ABX Micros 60 hematology analyzer (SN# 904CS98707). 2. Random review the laboratory's CBC RBC QC records from 2020-2021 on Horiba ABX Micros 60 hematology analyzer revealed 10 of 50 days reviewed with CBC RBC QC out of manufacturer's acceptable ranges without corrective actions. (L=Low, N=Normal, H=High) 9/21/21 RBC 4.38 QC Lot#: MX431N Exp: 2021-11-05 Ranges: 4.40-4.76 9/3/21 RBC 6.19 QC Lot#: MX431H Exp: 2021-11-05 Ranges: 5.64-6.04 8/30/21 RBC 6.20 QC Lot#: MX431H Exp: 2021-11-05 Ranges: 5.64-6.04 8/27/21 RBC 4.81 QC Lot#: MX430N Exp: 2021-09-05 Ranges: 4.44-4.80 8/25/21 RBC 6.11 QC Lot#: MX430H Exp: 2021-09-05 Ranges: 5.44-5.84 8/5/21 RBC 4.81 QC Lot#: MX430N Exp: 2021-09-05 Ranges: 4.44-4.80 7

	/30/21 RBC 2.54 QC Lot#: MX430L Exp: 2021-09-05 Ranges: 2.20-2.50 9/2/20 RBC 4.37 QC Lot#: MX424N Exp: 2020-09-05 Ranges: 4.38-4.74 8/27/20 RBC 5.24 QC Lot#: MX424H Exp: 2020-09-05 Ranges: 5.45-5.85 8/13/20 RBC 2.19 QC Lot#: MX424L Exp: 2020-09-05 Ranges: 2.21-2.51 3. Review of CMS 116 application signed by the CEO on 9/13/21 revealed the CBC annual volume was 45,726. 4. An interview with the lab coordinator on 9/22/21 at 12:18 pm in the breakroom confirmed no corrective actions documented for out of limit CBC QCs. Key: CBC=Complete Blood Count QC=Quality Control CMS=Center of Medicare and Medicaid Service CEO=Chief executive officer RBC=Red Blood Cell
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory's records and confirmed in an interview found the laboratory failed to establish laboratory QA policy for calibration/calibration verification and quality control procedures to monitor, assess, identify and correct problems in analytical systems on Horiba ABX Micro 60 hematology analyzer. The findings were: 1. Review of the laboratory's records revealed no documentation of laboratory's QA policy for calibration/calibration verification and quality control procedures in analytical systems on Horiba ABX Micros 60 (SN# 904CS98707). 2. An interview with the assistant manager of quality and the lab coordinator on 9/23/21 at 10:15 am in the conference room confirmed to have no written laboratory QA policy for analytical systems. Key: QA=Quality Assurance
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 4/22/21-9/8/21, and confirmed in an interview found the laboratory failed to provide verified normal ranges for five of five analytes reviewed, WBC, RBC, HGB, HCT, and PLT, for Horiba ABX Micros 60 hematology analyzer. (Refer D5421) 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 10 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 x10 3. Further review of 10 patient final reports revealed the laboratory did not include reference ranges specific to sex nor did they include pediatric ranges to be used by the individual interpreting

	the results. 4/22/21 Sex:F Specimen/Accession ID: 647570 4/30/21 Sex:M Specimen /Accession ID: 649095 6/14/21 Sex:M Specimen/Accession ID: 656231 8/12/21 Sex: M Specimen/Accession ID: 665327 8/12/21 Sex:F Specimen/Accession ID: 665368 9 /2/21 Sex:F Specimen/Accession ID: 669276 9/7/21 Sex:M Specimen/Accession ID: 669783 (Pediatric patient) 9/8/21 Sex:F Specimen/Accession ID: 670054 (Pediatric patient) 4. An interview with the lab coordinator on 9/23/21 at 10:33 pm in the conference room confirmed the above findings. Key: WBC=White Blood Cell RBC=Red Blood Cell HGB=Hemoglobin HCT=Hematocrit PLT=Platelets CBC=Complete Blood Count
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 Technical Consultant credentials provided for review 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 23, 2021 at 09:37 AM 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.