Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0660158	11/05/2025
Name of Provider or Supplier	**Street Address, City, State**	
Chca Woman's Hospital, Lp	7600 Fannin Street, Houston, 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
D0000	An announced validation survey of the laboratory was conducted on 11/04/2025 through 11/05/2025. The laboratory was found out of compliance with the CLIA regulations (42 CFR Part 493, Requirements for Laboratories). The CONDITIONS NOT MET were: D2016 - 42 C.F.R. 493.803 Condition: Successful participation [proficiency testing] D5400 - 42 C.F.R. 493.1250 Condition: Analytic systems D6076 - 42 C.F.R. 493.1441 Condition: Laboratories performing high complexity testing; laboratory director D6141 - 42 C.F.R. 493.1459 Condition: Laboratories performing high complexity testing; general supervisor
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on the review of the laboratory's policy, the proficiency testing records from 2024 to 2025, a list of testing personnel with areas of competency, and confirmed in an interview, the laboratory failed to ensure 3 of 4 routine chemistry proficiency testing events were analyzed by personnel who routinely perform chemistry testing in the laboratory. The findings were: 1. Review of the laboratory's policy titled "Laboratory Quality Management Plan", approved by the LD on 09/28/2025, under "PROFICIENCY TESTING" revealed "2. Proficiency testing samples will be integrated within the routine laboratory workload, and analyzed by personnel who routinely test patient samples in the same primary method systems as for patient samples." 2. Review of a list of testing personnel with areas of competency provided by the laboratory on 11/04/2025 revealed there were 15 testing personnel to perform routine chemistry. 3. Review of the CAP proficiency testing records from 2024 to 2025 revealed testing personnel#4 (as indicated on the CMS 209 form) attested to the

	analyzing 3 of 4 proficiency testing events for routine chemistry. NB2-A 2024 Neonatal Bilirubin, 2 challenges Testing personnel signed: TP#4 NB2-B 2024 Neonatal Bilirubin, 2 challenges Testing personnel signed: TP#4 NB2-B 2025 Neonatal Bilirubin, 5 challenges Testing personnel signed: TP#4 4. In an interview on 11/04/2025 at 1:40 pm in a conference room, the general supervisor #6 confirmed the above findings. Key: CMS=Center of Medicare and Medicaid Services TP=Testing personnel
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of the CMS Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile, onsite review of the laboratory's 2024 and 2025 College of American Pathologists (CAP) proficiency testing (PT) records and confirmed in an interview, the laboratory failed to attain successful performance for the analyte Albumin for two of three consecutive testing events, CAP 2024 C-B 2nd event and 2025 C-A 1st event, resulting in unsuccessful performance. Refer to D2096.
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f) (f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of the CMS Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile, onsite review of the laboratory's 2024 and 2025 College of American Pathologists (CAP) proficiency testing (PT) records and confirmed in an interview, the laboratory failed to attain successful performance for the analyte Albumin for two of three consecutive testing events, CAP 2024 C-B 2nd event and 2025 C-A 1st event, resulting in unsuccessful performance.

	The findings were: 1. Review of the CMS Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile revealed the laboratory failed to attain a satisfactory score of at least 80% in a specialty of routine Chemistry for a regulated analyte of Albumin for 2 of 3 consecutive proficiency testing events. CAP 2024 2nd event Albumin = 0% CAP 2025 1st event Albumin = 20% 2. Review of the laboratory's CAP PT records during an onsite survey for 2024 revealed the laboratory received unsatisfactory score of 0% for Albumin in 2024 2nd event. 3. Review of the laboratory's CAP PT records during an onsite survey for 2025 revealed the laboratory received unsatisfactory score of 20% for Albumin in 2025 1st event. 4. In an interview on 11/05/2025 at 3:05 pm, the general supervisor #6 (as indicated on CMS 209) confirmed the above findings. Key: CMS = Center for Medicare and Medicaid Services CAP = College of American Pathologist PT = Proficiency testing
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of manufacturer instructions, surveyor's observations, review of laboratory's test menu and volumes, new test/instrument verification studies, quality control records, patient test records and staff interview, the laboratory failed to meet analytic systems requirements for five of fifteen test platforms used by the laboratory in 2024 and 2025. Findings included: 1. The laboratory failed to follow its own policy when patient samples were assayed more than 30 minutes after collection on the Thromboelastograph- Coagulation (TEG) analyzer. Refer to D5401. 2. The laboratory failed to verify reference ranges for all specimen types on the iStat, and patient normal ranges on the Atelica analyzers. Refer to D5421 A and B. 3. The laboratory failed to have documentation of testing a control material with titered reactivity when patient's Rapid Plasma Reagin (RPR) titers were performed. Refer to D5451. 4. The laboratory failed to ensure one sample of control material was tested each 8 hours of testing on the i-Stat wireless analyzer. Refer to D5537.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, the laboratory's records, and staff interview, the laboratory failed to follow its own policy five of thirty one times when patient samples were assayed more than 30 minutes after collection on the

	Thromboelastograph- Coagulation (TEG) analyzer from January to August 2025. Findings include: 1. A review of the laboratory's policy titled 'Thromboeslatograph-Coagulation (TEG) Analyzer' revealed the following: "Assay the patient's sample within 30 minutes after collection." 2. A review of the laboratory's records from January to August 2025 revealed the following 5 patient's samples were received in the laboratory 30 minutes after collection: - Date: 2/18/25 Patient ID: F00038729383 Collection time: 10:06 Received: 11:47 Elapsed time: 101 minutes - Date: 4/12/25 Patient ID: F00038870089 Collection time: 18:24 Received: 20:43 Elapsed time: 139 minutes - Date: 5/23/25 Patient ID: F00038954546 Collection time: 13:37 Received: 14:15 Elapsed time: 38 minutes - Date: 8/8/25 Patient ID: F00039131838 Collection time: 16:03 Received: 16:42 Elapsed time:39 minutes - Date: 8/14/25 Patient ID: F00039131838 Collection time: 09:45 Received: 10:23 Elapsed time: 38 minutes 3. In an interview on 11/4/25 at 3:30 p.m. in the conference room, after review of the records, the hematology general supervisor confirmed the above findings.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on laboratory policy, and confirmed in interview, the laboratory procedure manual failed to document reference ranges for three of three specimen types tested on the i-Stat wireless analyzer in 2025. Findings included: 1. Review of laboratory policy, "I-Stat Procedure" (Approved by the laboratory director on 07/2025) revealed the following patient sample types used on the CG8+ cartridge in blood gas testing: a. Arterial b. Venous c. Finger (capillary) No reference ranges for the above specimen types were documented in the policy. The surveyor requested documentation of reference ranges for the above specimen types used on the CG8+ cartridge, tested on the i-Stat analyzer, and none were provided. 2. In an interview on 11/05/2025 at 01:48 PM, in the laboratory conference room, the point of care coordinator confirmed the laboratory procedure manual failed to document reference ranges for three of three specimen types tested on the i-Stat wireless analyzer in 2025.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

	CFR(s): 493.1252(a) (a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of provided manufacturer's instructions' manual, laboratory's policies /procedures, screenshot of programmed maintenance parameters on the instrument and staff interview, the laboratory failed to follow manufacturer's instructions in the operator's manual and own policies for instrument dispense pressure for one of one Siemens MicroScan Walkaway microbiology analyzer in use in 2024 and 2025. Findings included: 1. Review of laboratory's Siemens MicroScan Walkaway operator's manual (document 9020-6745, Revision A), revealed: "Dispense Pressure Normal Range: 2.8 - 3.2 psi" 2. Review of laboratory's policy "MicroScan Walkaway Daily Procedure" (policy number 17278872, last approved 01/2025) revealed: "8. Maintenance - Walkaway Computer Icon ... v. Check dispense system pressure on WA (Walkaway) monitor- 2.8 to 3.2 is acceptable." 3. Review of a screenshot of the MicroScan Walkaway analyzer's programmed dispense pressure revealed: "WalkAway Dispense Pressure Normal Range: 2.7-3.8 psi" 4. In an interview on 11/04 /2025 at 1200 hours in the conference room, the laboratory's general supervisor number five (as indicated on submitted Form CMS 209) confirmed the findings. Key: psi - Pounds per square inch
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(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: A. Based on facility staff interview, review of manufacturer instructions, laboratory policy, package inserts, verification documentation, patient documentation, and confirmed in interview, the laboratory failed to verify reference ranges for all specimen types used on the CG8+ cartridge, for two of three specimens performed on the i-Stat wireless analyzer in 2025. Findings included: 1. In a phone interview on 11 /05/2025 at 02:18 PM in the main laboratory, helicopter evacuation staff stated arterial, venous and capillary samples were used in patient testing on the CG8+ cartridge, performed on the i-Stat analyzer during patient transport. 2. Review of laboratory policy, "I-Stat Procedure" (Approved by the laboratory director on 07 /2025) revealed the following patient sample types tested on the CG8+ cartridge: a. Arterial b. Venous c. Finger (capillary) 3. Review of CG8+ i-Stat cartridge package insert, "i-STAT CG8+ Cartridge" (Revision: 29-June-2022) revealed the following manufacturer provided reference ranges for the above specimen types in blood gas testing: a. Venous pH: 7.31-7.41 PO2: 35-45 mmHg PCO2: 41-51 mmHg b. Arterial

pH: 7.31-7.41 PO2: 80-105 mmHg PCO2: 35-45 mmHg c. Capillary No reference ranges were provided by the manufacturer for capillary sample types. Further review revealed the following: "The reference ranges programmed into the analyzer and shown above are intended to be used as guides for the interpretation of results ... Performance Characteristics The typical performance of the i-Stat CG8+ cartridge with the i-Stat System are shown below. Precision ...The statistics for mean, standard deviation (SD), and coefficient of variance (CV) are represented below. This is representative data, results in individual laboratories may vary. ...The repeatability analysis was conducted using the data collected across multiple point of care sites. For each sample type, samples were grouped into subintervals based on their mean values. Sample Type Venous Whole Blood Arterial Whole Blood Capillary Whole Blood ... ... Whole blood precision may vary from site to site due to differences in sample handling and other site-specific variables." 4. Review of laboratory CG8+ i-Stat verification documentation revealed the laboratory failed to include venous and capillary samples in the CG8+ cartridge verification study for blood gas specimens. The surveyor requested documentation of the above sample types included in the reference range verification study, and no documentation was provided. 5. Review of i-Stat analyzer (Serial Number: 414722) stored patient information, revealed the laboratory performed the following capillary patient sample in July 2025: a. Analysis Date: 07/07/2025 Patient ID: Patient A (See Patient Alias List) (Note: This was the laboratory back up i-Stat analyzer.) The laboratory was unable to provide other patient documentation of venous or capillary patient sample testing, due to the in use i-Stat analyzer (Serial Number: 331410) being in the helivac unit. At the time of survey, the laboratory was also unable to retrieve patient data in the laboratory point of care middleware system, due to an outage in the system. 6. In an interview on 11/05/2025 at 01:48 PM, in the laboratory conference room, the point of care coordinator confirmed the laboratory failed to verify reference ranges for all specimen types used on the CG8+ cartridge, for two of three specimens performed on the i-Stat wireless analyzer in 2025. Word Key ID- Identification 44697 B. Based on the surveyor's direct observation, the review of the laboratory's verification studies, and confirmed in an interview, the laboratory failed to perform studies to verify the patient normal ranges were appropriate for the patient population for 48 of 48 analytes tested on Atellica chemistry analyzers from June 2024 to October 2025. The findings were: 1. Based on the surveyor's direct observation on 11/02/2025 at 9:30 am in the lab revealed 2 identical Siemens Atellica CI1900 chemistry analyzers. C1:SN# IRC006712330 C2:SN# IRC006732330 2. Review of the laboratory's verification records revealed the laboratory director signed on 05/28/2024. 3. In an interview on 11 /04/2025 at 10:40 am in a conference room, the general supervisor#6 (as indicated on the CMS 209 form) confirmed the 2 Atellica CI1900 performed the identical analytes and started patient testing in June 2024. 4. Further review of the laboratory's verification records revealed the laboratory failed to perform studies to verify the patient normal ranges were appropriate for the patient population for analytes tested on 2 of 2 Atellica chemistry analyzers from June 2024 to October 2025. Analytes performed on Siemens Atellica CI1900 chemistry analyzers: Acetaminophen Alanine Aminotransferase (ALT) Albumin Alkaline Phosphatase Ammonia Amylase Aspartate Aminotransferase (AST) Bilirubin, direct Bilirubin, total Blood urea nitrogen (BUN) B-type natriuretic peptide (BNP) Calcium Carbon Dioxide Chloride Chloride, urine Cholesterol C-Reactive protein Creatine Kinase Creatinine Creatinine, urine Ethyl Alcohol Free Thyroxine (FT4) T3 free (FT3) Thyroxine (T4) Gamma-Glutamyl Transferase (GGT) Gentamicin Glucose, CSF (spinal fluid) Glucose High-destiny cholesterol High sensitive troponin I Total human chorionic gonadotropin (hCG) Phosphorus Lactic acid Lactate Dehydrogenase Lipase Magnesium Phenobarbital Potassium Potassium, urine Prealbumin Salicylate Sodium Sodium,

	urine Thyroid-Stimulating Hormone (TSH) Total protein Total protein, CSF (spinal fluid) Triglycerides Uric acid Vancomycin 5. In an interview on 11/05/2025 at 12:35 pm in a conference room, the general supervisor#6 (as indicated on the CMS 209 form) confirmed the lab currently is using manufacturer's reference ranges. 6. In an interview on 11/05/2025 at 3:15 pm in a conference room, the general supervisor#6 (as indicated on the CMS 209 form) confirmed the above findings. Key: CMS=Center for Medicare and Medicaid Services 44698 C. Based on review of manufacturer's user manuals, surveyor's observations, review of laboratory's test menu, new test /instrument verification studies, test volumes and staff interview, the laboratory failed to ensure positivity of all molecular assay targets were verified for two of four VERIGENE Processors SP used by the laboratory in 2025. Findings included: 1. Review of manufacturer's "Luminex VERIGENE System User Manual" (document 89-00002-00-591 Revision B, March 2020) revealed: "Independent Test Processing Modules: Each Processor SP can be randomly accessed, allowing for processing of different types of tests in multiple Processor SP units." 2. Surveyor's observations on 11/04/2025 at around 1330 hours in the laboratory revealed there were four tandem VERIGENE Processors SP (A:1, A:2, A:3, A:4) attached to one VERIGENE Reader and computer unit. These were: Processor A:1, Serial Number (SN) 13060075 Processor A:2, SN 13060076 Processor A:3, SN 13060077 Processor A:4, SN 13060078 3. Review of laboratory's test menu revealed the VERIGENE test system was used to test the "VERIGENE Respiratory Pathogens Flex Nucleic Acid Test (RP Flex)" with the following targets reported by the laboratory: Influenza A Influenza A /H1 Influenza A/H3 Influenza B RSV (Respiratory Syncytial Virus) A RSV B Adenovirus hMPV (Human Metapneumovirus) 4. Review of laboratory's test verification studies for the VERIGENE RP Flex Test and the VERIGENE test system completed in May 2025 revealed the laboratory did not verify all target positivity for each of the four VERIGENE tandem Processors as follows: a. Processor A:3 had no documented verification of positivity for: Adenovirus hMPV b. Processor A:4 had no documented verification of positivity for: Influenza A Influenza A/H1 Influenza A/H3 RSV A RSV B 5. Review of laboratory's test volumes from July, August and September 2025 revealed the laboratory tested 134 RP Flex Test samples in the three-month interval. It could not be determined, at the time of the survey, which samples were tested on Processors A:3 and A:4. 6. In an interview on 11/04/2025 at 1410 hours in the conference room, the laboratory's general supervisor number five (as indicated on submitted Form CMS 209) stated that the manufacturer completed the verification studies, and they considered the VERIGENE Test System as one instrument. The laboratory was not aware that each Processor was an instrument in itself. This confirmed the findings.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) (a)(2) Function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturers established limits before patient testing is conducted. (b) Equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer. The laboratory must do the following: This STANDARD is not met as evidenced by: Based on review of laboratory's policies/procedures, instrument maintenance records, test volumes and staff interview, the laboratory failed to ensure the Siemens

	MicroScan Walkaway microbiology analyzer's temperature and dispense pressure were documented for 28 of 62 days the instrument was in use in July and August 2025. Findings included: 1. Review of laboratory's policy "MicroScan Walkaway Daily Procedure" (policy number 17278872, last approved 01/2025) revealed: "8. Maintenance - Walkaway Computer Icon ... c. Check and record temperatures. ... v. Check dispense system pressure on WA monitor- 2.8 to 3.2 is acceptable." 2. Review of laboratory's MicroScan Walkaway maintenance records from July and August 2025 revealed the following 28 of 62 days reviewed, the instrument's temperature and dispense pressure were not documented: Date: 07/01/2025 07/02/2025 07/07/2025 07/09/2025 07/10/2025 07/12/2025 07/13/2025 07/16/2025 07/17/2025 07/21/2025 07/22/2025 07/23/2025 07/28/2025 07/29/2025 08/04/2025 08/06/2025 08/07/2025 08/11/2025 08/12/2025 08/13/2025 08/15/2025 08/18/2025 08/20/2025 08/21/2025 08/22/2025 08/26/2025 08/27/2025 08/28/2025 3. Review of laboratory's test volumes for July and August 2025 revealed the laboratory performed 179 tests on the MicroScan Walkaway test system in the two-month period. 4. In an interview on 11/04/2025 at 1200 hours in the conference room, the laboratory's general supervisor number five (as indicated on submitted Form CMS 209) confirmed the findings.
D5451	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(iii)(g) (d)(3)(iii) Test procedures producing graded or titered results, include a negative control material and a control material with graded or titered reactivity, respectively; This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, the laboratory's records, and staff interview, the laboratory failed to have documentation of testing a control material with titered reactivity on 24 of 24 days patient's Rapid Plasma Reagin (RPR) titers were performed from January to August 2025. Findings include: 1. A review of the laboratory's policy titled 'RPR' revealed the following: "Confirm reactive results by retesting the sample using the semiquantitative procedure. Interpretation of Results-Semiquantitative: The highest dilution in which visible aggregation occurs is considered the endpoint titer. " *There was no mention in the laboratory's policy of testing control material with titered reactivity when performing the semiquantitative procedure (RPR titer) on patient samples. 2. A review of the laboratory's records from January to August 2025 revealed the following 24 days when RPR titers were performed on patients and there was no documentation of titered control material being run: 1/20/25 Patient IDs: F00038704760, F00038703872, F00038707183 2/17/25 Patient ID: F00038764319 3/6/25 Patient ID: F00038806605 3/10/25 Patient ID: F00038812330 3/18/25 Patient ID: F00038745747 3/31/25 Patient ID: F00038859108 4/1/25 Patient ID: F00038859131 4/3/25 Patient ID: F00038868483 4/27/25 Patient IDs: F00038916880, F00038916891, F00038917347 5/23/25 Patient ID: F00038972515 5/27/25 Patient ID: F00038972617 6/20/25 Patient IDs: F00039031246, F00039032510 6/21/25 Patient IDs: F00039032576, F00039033271 6/22/25 Patient ID: F00039033351 6/30/25 Patient ID: F00038991983 7/1/25 Patient IDs: F00039052912, F00039053957 7/6/25 Patient IDs: F00039062254, F00039062312, F00039062856 7/7/25 Patient ID: F00039005788 7/10/25 Patient IDs: F00038916095, F00039070936 7/18/25 Patient ID: F00039079173 7/29/25 Patient ID: F00039112277 8/21/25 Patient IDs: F00039162493, F00039162562, F00039162584 8/27/25 Patient ID: F00039140679 8/28/25 Patient ID: F00039175772 3. In an interview on 11/5/25 at 10:30 a.m. in the conference room, after review of the records, the hematology general supervisor confirmed the above findings.

D5455	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(v)(g) (d)(3)(v) 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 molecular amplification procedure, include two control materials and, if reaction inhibition is a significant source of false negative results, a control material capable of detecting the inhibition. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory's policies/procedures, test verification studies, test menu, quality control (QC) records, test volumes and staff interview, the laboratory failed to document positive and negative QC for each of the four of four VERIGENE Processor SP instruments (A;1, A:2, A:3, and A:4) used by the laboratory in July and August 2025. Findings included: 1. Review of laboratory's policy "Respiratory Pathogens (RP) Flex Nucleic Acid Test - Verigene" (document 18236512, last approved 06/2025) revealed: "External control will be performed under the following situations: 1.With each new shipment of reagent or at least every 30 days." 2. Review of laboratory's test verification studies for the Verigene RP Flex Nucleic Acid Test (approved 05/28/2025) revealed the laboratory performed Individualized Quality Control Plan (IQCP) defining quality control (QC) frequency as every 30 days. 3. Review of laboratory's test menu revealed the VERIGENE test system was used to test the "VERIGENE Respiratory Pathogens Flex Nucleic Acid Test (RP Flex)" with the following targets reported by the laboratory: Influenza A Influenza A/H1 Influenza A/H3 Influenza B RSV (Respiratory Syncytial Virus) A RSV B Adenovirus hMPV (Human Metapneumovirus) 4. Review of laboratory's QC records for July and August 2025 revealed the laboratory documented RP Flex Test QC as follows: July 2025: A:1 Processor SP - No positive controls were tested in July 2025. A:2 Processor SP - No positive controls were tested in July 2025. A:3 Processor SP - No positive or negative controls were tested in July 2025. A:4 Processor SP - No negative control was tested in July 2025. August 2025: A:1 Processor SP - No positive or negative controls were tested in August 2025. A:2 Processor SP - No negative control or Influenza A, Influenza A/H1 or Influenza A/H3 positive controls were tested in August 2025. A:3 Processor SP - No positive controls were tested in August 2025. A: 4 Processor SP - No negative control or Influenza B, RSV A, RSV B, Adenovirus and hMPV positive controls were tested in August 2025. 5. Review of laboratory's test volumes revealed the laboratory tested 91 RP Flex Test samples in July and August 2025. It could not be determined, at the time of the survey, which samples were tested on each Processor. 6. In an interview on 11/04/2025 at 1500 hours in the conference room, the laboratory's general supervisor number five (as indicated on submitted Form CMS 209) stated that the laboratory rotated QC materials among all four Processors and was not aware that each Processor was an instrument in itself that required positive and negative external QC for each target. This confirmed the findings.
D5537	ROUTINE CHEMISTRY CFR(s): 493.1267(b)(d) (b) Test one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values on each day of testing.

This STANDARD is not met as evidenced by:
Based on surveyor observation, review of manufacturer's instructions, laboratory policy, quality control records in 2025, patient final reports, and confirmed in interview, the laboratory failed to test one sample of control material each 8 hours of testing on the i-Stat wireless analyzer, using the CG8+ cartridge for 42 of 42 days in 2025 (January-August 2025). Findings included: 1. During a tour of the facility on 11 /05/2025 at 10:18 AM, the surveyor observed the following CG8+ cartridge blood gas analytes performed on the i-Stat wireless analyzer: CG8+ Blood Gas Analytes: pH PCO2 PO2 2. Review of manufacturer instructions, "i-Stat 1 System Manual" (Revision Date: 18-October-2021) revealed the following: "QUALITY CONTROL FOR i-STAT CARTRIDGES AND THE ANALYZER'S CARTRIDGE TEST CYCLE ... Verify Performance of Analyzers Daily ... Quality control regimens should be established using information from the manufacturer and scientific literature." 3. Review of laboratory policy, "I-Stat Procedure" (Approved by the laboratory director on 07/2025) revealed the following: " ...Controls Liquid controls should be tested with each new lot or shipment of cartridges, and as indicated according to the IQCP." Review of laboratory policy, "IQCP i-Stat QC Plan" (Approved by the laboratory director on 07/2025) revealed the following: " ...As needed QC Test liquid controls with each new lot or shipment of cartridges ...NOTE: Regarding Liquid QC i-Stat does not require 2 levels of QC material be run on a monthly basis. Each cartridge offered for testing must pass 2 levels of QC once a quarter at a minimum." Further review of the laboratory IQCP policy, revealed the laboratory failed to perform an IQCP for the CG8+ cartridge. The surveyor requested documentation of the laboratory performing an IQCP to reduce the frequency of liquid quality control performance on the CG8+ cartridges, and none was provided. 4. Review of CG8+ quality control documentation in 2025 and patient final reports revealed the laboratory failed to perform quality control every 8 hours of patient testing for 42 of 42 patient testing days in 2025: January 2025 a. 01/02/2025 Patient Identification (ID): Patient 1-See Patient Alias List b. 01/03/2025 Patient Identification (ID): Patient 2-See Patient Alias List c. 01/04/2025 Patient Identification (ID): Patient 3-See Patient Alias List d. 01/16/2025 Patient Identification (ID): Patient 4-See Patient Alias List e. 01/22/2025 Patient Identification (ID): Patient 5-See Patient Alias List f. 01/26/2025 Patient Identification (ID): Patient 6-See Patient Alias List g. 01/27/2025 Patient Identification (ID): Patient 7-See Patient Alias List h. 01/31/2025 Patient Identification (ID): Patient 8-See Patient Alias List February 2025 i. 02/06/2025 Patient Identification (ID): Patient 9-See Patient Alias List j. 02/17/2025 Patient Identification (ID): Patient 10-See Patient Alias List k. 02/20/2025 Patient Identification (ID): Patient 11-See Patient Alias List l. 02/25/2025 Patient Identification (ID): Patient 12-See Patient Alias List March 2025 m. 03/01/2025 Patient Identification (ID): Patient 13-See Patient Alias List n. 03/05/2025 Patient Identification (ID): Patient 14-See Patient Alias List o. 03/14/2025 Patient Identification (ID): Patient 15-See Patient Alias List p. 03/29/2025 Patient Identification (ID): Patient 16-See Patient Alias List April 2025 q. 04/01/2025 Patient Identification (ID): Patient 17-See Patient Alias List r. 04/04/2025 Patient Identification (ID): Patient 18-See Patient Alias List s. 04/17/2025 Patient Identification (ID): Patient 19-See Patient Alias List t. 04/23/2025 Patient Identification (ID): Patient 20-See Patient Alias List May 2025 u. 05/01/2025 Patient Identification (ID): Patient 21-See Patient Alias List v. 05/07/2025 Patient Identification (ID): Patient 22-See Patient Alias List w. 05/23/3035 Patient Identification (ID): Patient 23-See Patient Alias List x. 05/24/2025 Patient Identification (ID): Patient 24-See Patient Alias List y. 05/28/2025 Patient

	Identification (ID): Patient 25-See Patient Alias List June 2025 z. 06/03/2025 Patient Identification (ID): Patient 26-See Patient Alias List aa. 06/11/2025 Patient Identification (ID): Patient 27-See Patient Alias List ab. 06/19/2025 Patient Identification (ID): Patient 28-See Patient Alias List ac. 06/21/2025 Patient Identification (ID): Patient 29-See Patient Alias List ad. 06/29/2025 Patient Identification (ID): Patient 30-See Patient Alias List July 2025 ae. 07/07/2025 Patient Identification (ID): Patient 31-See Patient Alias List af. 07/12/2025 Patient Identification (ID): Patient 32-See Patient Alias List ag. 07/20/2025 Patient Identification (ID): Patient 33-See Patient Alias List ah. 07/26/2025 Patient Identification (ID): Patient 34-See Patient Alias List ai. 07/28/2025 Patient Identification (ID): Patient 35-See Patient Alias List aj. 07/29/2025 Patient Identification (ID): Patient 36-See Patient Alias List August 2025 ak. 08/04/2025 Patient Identification (ID): Patient 37-See Patient Alias List al. 08/07/2025 Patient Identification (ID): Patient 38-See Patient Alias List am. 08/08/2025 Patient Identification (ID): Patient 39-See Patient Alias List an. 08/12/2025 Patient Identification (ID): Patient 40-See Patient Alias List ao. 08/18/2025 Patient Identification (ID): Patient 41-See Patient Alias List ap. 08/29/2025 Patient Identification (ID): Patient 42-See Patient Alias List 5. In an interview on 11/05/2025 at 01:35 PM, in the facility conference room, the point of care coordinator confirmed the laboratory failed to test one sample of control material each 8 hours of testing on the i-Stat wireless analyzer, using the CG8+ cartridge for 42 of 42 days in 2025 (January-August 2025). Word Key pH- Potential of Hydrogen PCO2- Partial Pressure of Carbon Dioxide PO2- Partial Pressure of Oxygen QC- Quality Control IQCP- Individualized Quality Control Plan
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. This STANDARD is not met as evidenced by: Based on review of laboratory policy, Ortho Vision comparison studies in 2024, and confirmed in interview, the laboratory failed to perform one of two analyzer comparison studies in 2024. Findings included: 1. Review of laboratory policy, "Ortho Vision Correlation of Instrument Manual Method Results" (Approved by the laboratory director on 07/2025) revealed the following: "Principle/Purpose: Twice a year, results obtained for patient specimens both Ortho Vision analyzers will be compared ... Equipment and Reagents: Ortho Vision Serial Numbers: J#50002113 and J#50002114 ...For each analyzer, obtain the following samples: Type and Screen: 8 Minimum Samples Cord Blood: 8 Minimum Samples Antibody Panel: 2-3 Minimum Samples" 2. Review of laboratory comparison studies in 2024, revealed the laboratory failed to perform one of two comparison studies on the Ortho Vision analyzers in 2024. The surveyor requested the above documentation, and none was provided. 3. In an interview on 11/04/2025 at 03:16 PM in the blood bank area, the blood bank lead confirmed the laboratory failed to perform one of two analyzer comparison studies in 2024.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441

	The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of manufacturer instructions, laboratory's policies/procedures, test verification studies, quality control records, test volumes, patient test records, proficiency testing records and staff interview, the laboratory's director failed to provide overall management and direction of the laboratory for three of fifteen test platforms used by the laboratory in 2024 and 2025. Findings included: 1. Laboratory director failed to ensure laboratory's verification studies were adequate. Refer to D6086. 2. Laboratory director failed to ensure laboratory attained successful performance for the analyte Albumin for two of three consecutive proficiency testing events from 2024 and 2025. Refer to D6089. 3. Laboratory director failed to ensure laboratory's quality control was maintained. Refer to D6093. 4. Laboratory director failed to ensure laboratory's personnel had adequate experience. Refer to D6101.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by: Based on review of manufacturer's user manuals, surveyor's observations, review of laboratory's test menu, new test/instrument verification studies, test volumes and staff interview, the laboratory director failed to ensure laboratory's verification studies were adequate for two of two test systems with incomplete verification studies used by the laboratory in 2024 and 2025. Refer to D5421 A and B.
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) (e)(4)(i) The proficiency testing samples are tested as required under subpart H of this part; This STANDARD is not met as evidenced by: Based on review of the CMS Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile, onsite review of the laboratory's 2024 and 2025 College of American Pathologists (CAP) proficiency testing (PT) records and confirmed in an interview, the laboratory director failed to ensure laboratory attained successful performance for the analyte Albumin for two of three consecutive testing events, CAP 2024 C-B 2nd event and 2025 C-A 1st event, resulting in unsuccessful performance. Refer to D2096.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established

	and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on review of laboratory's quality control records and staff interview, the laboratory director failed to ensure laboratory's quality control was maintained for two of eleven laboratory's automated test platforms used in 2024 and 2025. Refer to D5537.
D6101	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(11) (e)(11) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart; This STANDARD is not met as evidenced by: Based on review of laboratory's personnel records and staff interview, the laboratory director failed to ensure one of twelve general supervisors employed by the laboratory in 2024 and 2025 had adequate experience for the position. Refer to D6143.
D6141	GENERAL SUPERVISOR CFR(s): 493.1459 The laboratory must have one or more general supervisors who are qualified under 493.1461 of this subpart to provide general supervision in accordance with 493.1463 of this subpart. This CONDITION is not met as evidenced by: Based on review of laboratory's personnel records and staff interview, the laboratory failed to ensure one of twelve general supervisors employed by the laboratory in 2024 and 2025 qualified for the position. Refer to D6143.
D6143	GENERAL SUPERVISOR QUALIFICATIONS CFR(s): 493.1461 (a) The general supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and (b) The general supervisor must be qualified as a-- (b)(1) Laboratory director under 493.1443; or (b)(2) Technical supervisor under 493.1449. (c) If the requirements of paragraph (b)(1) or (2) of this section are not met, the individual functioning as the general supervisor must-- (c)(1)(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 or have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; and (c)(1)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing; or (c)(2)(i) Qualify as testing personnel under 493.1489(b)(3); and (c)(2)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing; or (c)(3) Meet the

	requirements at 493.1443(b)(3) or 493.1449(c)(4) or (5); or (c)(4) Notwithstanding any other provision of this section, an individual is considered qualified as a general supervisor under this section if they were qualified and serving as a general supervisor in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. (d) For blood gas analysis, the individual providing general supervision must-- (d)(1) Be qualified under 493.1461(b)(1) or (2), or 493.1461(c); or (d)(2)(i) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (d)(2)(ii) Have at least one year of laboratory training or experience, or both, in blood gas analysis; or (d)(3)(i) Have earned an associate degree related to pulmonary function from an accredited institution; and (d)(3)(ii) Have at least two years of training or experience, or both in blood gas analysis. (e) The general supervisor requirement is met in histopathology, oral pathology, dermatopathology, and ophthalmic pathology because all tests and examinations, must be performed: (e)(1) In histopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or (f)(1); (e)(2) In dermatopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(f)(2); (e)(3) In ophthalmic pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(f)(3); and (e)(4) In oral pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or (g). This STANDARD is not met as evidenced by: Based on review of laboratory's personnel records and staff interview, the laboratory failed to ensure one of twelve general supervisors (GS) employed by the laboratory in 2024 and 2025 qualified for the position, GS number six. Findings included: 1. Review of laboratory's personnel records revealed GS number six was employed by the facility at the beginning of 2025, with initial competency assessments documented on 03/14/2025. 2. Further review of the personnel records for GS number six revealed there was no documentation of experience available for review, necessary to qualify the individual for the GS position. 3. In an interview on 11/04/2025 at 1500 hours in the conference room, the laboratory's general supervisor number six (as indicated on submitted Form CMS 209) confirmed the findings.