Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2087498	08/30/2022
Name of Provider or Supplier	**Street Address, City, State**	
Alliance Hospital Group Llc Dba Alliance Hospital	17506 Red Oak Dr, 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	The laboratory was found out of compliance with the following CONDITION LEVEL DEFICIENCIES: D2000 - 42 C.F.R. 493.801 Condition: Enrollment and testing of samples D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the CMS Southern Operations Branch-Dallas for referral to the Office of Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on a review of the laboratory proficiency testing (PT) records, review of random patient test results for August 22 to August 25 of 2022 and staff interview, it

	was determined the laboratory failed to enroll in a HHS (Health and Human Services) approved proficiency testing program for 2 of 2 of the laboratory's testing specialties with regulated analytes requiring PT enrollment (Chemistry and Hematology). Findings included: 1. A review of available proficiency testing records revealed that there was no documentation of the laboratory being enrolled in a proficiency testing program at the time of the survey for the regulated analytes in the specialties of Hematology and Chemistry. 2. Review of random patient test results for August 22 to August 25 of 2022 revealed that the facility performed testing of the following analytes requiring PT enrollment: In the specialty of Chemistry: Alanine aminotransferase (ALT/SGPT) Albumin Alcaline Phosphatase Aspartate aminotransferase (AST/SGOT) Bilirubin, Total Calcium Carbon Dioxide Chloride Creatinine Potassium Sodium Total Protein Urea Nitrogen (BUN) In the Specialty of Hematology: Cell Identification (Differential) Erythrocyte Count (RBC) Hematocrit Hemoglobin Leukocyte Count Platelet Count 3. In an interview on 08/29/2022 at 1130 hours in the break room, the laboratory's Technical Consultant confirmed that the facility was not enrolled in proficiency testing.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of submitted Form 116, review of the laboratory's personnel competency assessment records for 2021 and 2022 and staff interview, it was determined the laboratory failed to document competency assessment for one of one Technical Consultant, Technical Supervisor and General Supervisor employed by the laboratory. Findings included: 1. Review of submitted Form 116 revealed the laboratory employed one person holding the roles of Technical Consultant, Technical Supervisor and General Supervisor. 2. Review of the laboratory's personnel competency assessment records for 2021 and 2022 revealed there were no competency assessments documented for the facility's Technical Consultant, the Technical Supervisor and the General Supervisor. 3. In an interview on 08/29/2022 at 1545 hours in the break room, the laboratory's Consultant and the Technical Supervisor confirmed the findings.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions for use for Molecular PCR (polymerase chain reaction) test panels, review of the laboratory's policies and

	procedures, and staff interview, it was determined the laboratory failed to specify to provider specimen collection device, specimen storage and transport requirements for 3 of 3 in-house developed PCR tests performed by the laboratory. Findings included: 1. Review of the manufacturer's instructions for use and laboratory procedures for test panels used in the facility's laboratory developed PCR testing revealed the following specimen requirements: a. For Bioeksen Bio-Speedy Direct RT-qPCR SARS-CoV-2 panel, the manufacturer's instructions for use (version 202105251755EAG) revealed: "Collecting the Specimen ...Swabs (dacron or polyester flocked) should be placed into immediately into a sterile transport tube containing 2-3 mL of viral transport medium (VTM)... Nosopharyngeal (NP) or nasal aspirate and nasal wash samples should be transferred into sterile containers containing 2-3 mL of VTM (in case of immediate analysis, these samples can be taken into sterile containers by healthcare providers). Bronchoalveolar lavage (BAL) samples should be collected 2-3 mL into a sterile leak-proof, screw-cap sputum collection cup or sterile dry container. Transporting Specimens ...Store specimens at 2-8C and ship overnight to the laboratory on ice pack." AND "Warnings and Precautions: ...12) ...Cotton or calcium alginate swabs or swabs with wooden sticks should not be used since they may inactivate some viruses and inhibit PCR." b. For the Bioeksen Bio-Speedy Respiratory Tract RT-qPCR MX-24T Panel, the manufacturer's instructions for use (version 202206071223SK) revealed: "Collection, Storage, and Shipment of Clinical Specimens ... Swab samples are transferred into the vNAT Transfer Tube... containing 2 mL of the vNAT reagent or into a sterile transport tube containing 3 mL of Viral Transport Medium (VTM). Bronchoalveolar lavage and nasopharyngeal aspirate samples should be transferred into sterile containers containing 3 mL of VTM (in case of immediate analysis, these samples can be taken into sterile containers by healthcare providers). Other sample types (saliva, gargle, and sputum) should be transferred into preservative-free sterile tubes. ... Store the specimens in the VTM or preservative-free sterile containers at 2-8C and ship overnight to the laboratory on ice pack. ... specimens in the VTM or preservative-free sterile containers can be stored at 2-8C for up to 72 hours..." AND "Warnings ...9. Cotton or calcium alginate swabs or swabs with wooden sticks should not be used since they may inactivate some viruses and inhibit PCR." c. For Bioeksen Bio-Speedy Sepsis qPCR MX-30T Panel used for wound sepsis determination the laboratory developed its own procedure (SOP 020 Bio-Speedy MX-30S Wound Sepsis, last approved by laboratory director on 08/27/2022) specifying sample requirements as follows: "ACCEPTABLE SPECIMEN COLLECTION TYPE -eSwab (Copan 480C) VTM Wound swab only. Use only the provided Nucleo-Safe specimen collection swabs. Do not use calcium alginate swabs or swabs with wooden shafts, as they may contain substances that inactivate some viruses and inhibit PCR testing. Place swab immediately into the eSwab VTM tube." 2. Review of the laboratory's policy CL001 "Specimen Collection, Handling and Storage" (available to providers and last approved by laboratory director on 08/25/2022) revealed: "PROCEDURES FOR SWAB COLLECTION Swab collection for the following specimens: a. COVID and RPP: collect nosopharyngeal swabs, oropharyngeal (throat) swabs, combined nasopharyngeal/oropharyngeal swabs, anterior nasal swabs, mid-turbinate nasal swabs, nasal or nasopharyngeal aspirates, nasal washes, and bronchoalveolar lavage samples from individuals suspected of COVID-19 or respiratory infection. b. Wound, by medically qualified personnel collect specimen using sterile swab. c. Stool, by medically qualified collect rectal swab or dip/soak the swab in stool container and send to the lab." This policy did not give the provider specifications for collection devices (swabs/tubes/transport media) and specimen storage and transport requirements. 3. In an interview on 08/30/2022 at 0945 hours in the break room, the laboratory's Technical Supervisor, after review of the data, confirmed the findings.

D5401	PROCEDURE MANUAL CFR(s): 493.1251(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 review of a random Sysmex XN-530 hematology analyzer's test result printout, review of the Sysmex XN-530 hematology analyzer's Flagging Interpretation Guide, review of laboratory's policies and procedures and staff interview, it was determined the laboratory failed to address flagged results in the Hematology policies and procedures. Findings included: 1. Review of a random Sysmex XN-530 hematology analyzer's test resul printout (accession number B222240021) revealed multiple results flagged with an asterisk (*) as follows: Component: Result: WBC (White blood cells) 11.73* PLT (Platelets) 124* NEUT (neutrophils) 6.05* LYMPH (Lymphocytes) 2.84* Mono (Monocytes) 0.32* EO (Eosinophils) 0.04* BASO (Basophils) 1.04* IG (Immature granulocytes) 1.44* 2. Further review of the above instrument printout revealed the following IP (Instrument Protocol) and Action Messages: "WBC IP Message WBC Abn (abnormal) Scattergram Basophilia IG Present ... PLT IP Message PLT Abn Distribution PLT Clump?" And action messages: "#1WBCAbnScat SEND TO REFERENCE LAB #4:Blast/AbnLym, SEND TO REFERENCE LAB #14:SEND OUT TO REFERENCE LAB" 3. Review of the Sysmex XN-530 hematology analyzer's Flagging Interpretation Guide (Document Number 139-LSS, Rev. 2) revealed: "The asterisk (*) indicates these results may be unreliable and should be confirmed according to your laboratory protocol prior to reporting." 4. Review of laboratory's Hematology policies and procedures revealed the policies/procedures did not address flagged results. 5. In an interview on 08/30/2022 at 1255 hours in the break room, the laboratory's Technical Consultant, after review of the data, confirmed the findings.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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 surveyors observations, review of ClearChem Diagnostics manufacturer's instructions for use for chemistry testing reagent for urea nitrogen (BUN) in serum and staff interview, it was determined the laboratory failed to follow manufacturer instructions for calibrators used on the Beckman Coulter AU680, one of two chemistry analyzers. Findings included: 1. Surveyors observations on 08/30/2022 at 11:25 in the laboratory revealed the following chemistry calibrators in use stored in the refrigerator: Beckman Coulter Lyophilized Chemistry Calibrator 1 Lot: 9610101 Expiration date: 2023-5-31 Amended expiration date: 09/12/2022 Beckman Coulter Lyophilized Chemistry Calibrator 2 Lot: 9610201 Expiration date: 2023-5-31 Amended expiration date: 09/12/2022 2. Review of the ClearChem Diagnostics

	manufacturer's instructions for use for the testing reagent for urea nitrogen (BUN) in serum revealed: "CALIBRATION Use King's serum based calibrator (catalog number 80194)." 3. In an interview on 08/30/2022 at 1135 hours in the break room, the laboratory's Technical Consultant stated that he was unaware that the manufacturer's package insert requirement was to use King's calibrators. This confirmed the findings.
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 verification studies for the laboratory's hematology and chemistry test systems and staff interview, it was determined the laboratory failed to document complete verification studies prior to reporting patient test results for 3 of 3 analyzers in use. Findings included: 1. Review of the verification studies for the laboratory's hematology and chemistry test systems revealed no documentation of verification of the following performance characteristics for 3 of 3 analyzers in use: Specialty: Chemistry Analyzer: Beckman Coulter AU680 No documentation for: Reference intervals (normal values) verification Specialty: Chemistry Analyzer: Beckman Coulter Access 2 No documentation for: Reference intervals (normal values) verification Specialty: Hematology Analyzer: Sysmex XN-530 No documentation for: Reference intervals (normal values) verification 2. In an interview on 08/30/2022 at 1010 hours in the break room, the laboratory's Technical Consultant, after review of the data, confirmed the findings.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: A. Based on review of the manufacturer's instructions for use for the laboratory's Bioeksen Bio-Speedy Respiratory Tract RT-qPCR MX-24T Panel processed on the BIORAD CFX 384 Opus analyzer, review of the laboratory's establishment /performance verification studies for the same panel, review of patient test reports and

	staff interview, it was determined the laboratory's establishment studies failed to document verification of detection capability of 3 of 24 microbial targets reported by the laboratory, and evaluation of interfering substances. Findings included: 1. Review of the manufacturer's instructions for use for the Bioeksen Bio-Speedy Respiratory Tract RT-qPCR MX-24T Panel (version 202206071223SK) revealed the panel is capable of detecting the following microbial targets: SARS-CoV-2 Influenza A Influenza B Human Corona 229E Human Corona OC43 Human Corona NL63 Human Corona HKU1 Human Parainfluenza 1 Human Parainfluenza 2 Human Parainfluenza 3 Human Parainfluenza 4 Human Metapneumovirus Enterovirus/ Human Rhinovirus Oligo Set 1 Adenovirus Human Bocavirus Human Parechovirus Enterovirus/ Human Rhinovirus Oligo Set 2 Legionella pneumophila Mycoplasma pneumoniae Chlamydophila pneumoniae Heamophilus influenzae Bordetella pertusis Streptococcus pneumoniae Respiratory syncytial virus A/B 2. Review of the laboratory's establishment studies for the above panel revealed the following 3 of 24 microbial targets did not have documentation of verification of detection capability: Human Corona HKU1 Human Parainfluenza 1 Human Bocavirus 3. Review of random patient test reports revealed the laboratory reported detection and/or non-detection of all 24 microbial targets. 4. Further review of the establishment studies for the above panel revealed there was no documentation of evaluation of potential interfering substances that may affect test performance characteristics. 5. In an interview on 08/30/2022 at 1430 hours in the break room, the laboratory's Technical Supervisor, after review of the data, confirmed the findings. B. Based on review of laboratory's policies and procedures, review of the laboratory's establishment studies for the Bioeksen Bio-Speedy Direct RT-qPCR SARS-CoV-2 panel processed on the BIORAD CFX 384 Opus analyzer and staff interview, it was determined the laboratory's establishment studies failed to document verification of performance for 2 of 3 specimen transport systems identified in the laboratory's test procedure for the said panel, and evaluation of interfering substances. Findings included: 1. Review of the laboratory's procedure "Bio-Speedy Direct RT-qPCR SARS-CoV-2" (SOP 019; last reviewed 08/28/2022) revealed: "ACCEPTABLE SPECIMEN COLLECTION TYPES: 1. eSwab VTM (Nasopharyngeal & Oropharyngeal swabs) 2. vNAT VTM (Nasopharyngeal & Oropharyngeal swabs) 3. Poyton VTM (Nasopharyngeal & Oropharyngeal swabs)" 2. Review of the laboratory's establishment studies for the Bioeksen Bio-Speedy Direct RT-qPCR SARS-CoV-2 panel processed on the BIORAD CFX 384 Opus analyzer revealed the establishment study was performed using only the vNAT VTM. The eSwab VTM and Poyton VTM were not included in the study. 3. Further review of the establishment studies for the above panel revealed there was no documentation of evaluation of potential interfering substances that may affect test performance characteristics. 4. In an interview on 08/30/2022 at 1445 hours in the break room, the laboratory's Technical Supervisor, after review of the data, confirmed the findings. C. Based on review of the laboratory's establishment studies for the in-house developed wound sepsis determination by Bioeksen Bio-Speedy Sepsis qPCR MX-30T Panel processed on the BIORAD CFX 384 Opus analyzer and staff interview, it was determined the laboratory's establishment studies failed to document evaluation of interfering substances. Findings included: 1. Review of the laboratory's establishment studies for the Bioeksen Bio-Speedy Sepsis qPCR MX-30T Panel processed on the BIORAD CFX 384 Opus analyzer revealed there was no documentation of evaluation of potential interfering substances that may affect test performance characteristics. 2. In an interview on 08/30/2022 at 1500 hours in the break room, the laboratory's Technical Supervisor, after review of the data, confirmed the findings.
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 laboratory's quality control records for the Beckman Coulter AU680 and the Beckman Coulter Access 2 chemistry analyzers for August of 2022, review of laboratory's policies and procedures and staff interview, it was determined the laboratory failed to have in place a system to monitor over time test performance for 2 of 2 chemistry analyzers in use. Findings included: 1. Review of the laboratory's quality control records for the Beckman Coulter AU680 and the Beckman Coulter Access 2 chemistry analyzers for August of 2022 revealed there was no documentation of overtime monitoring of test performance for either of the chemistry analyzers. 2. Review of laboratory's policies and procedures revealed there was no policy/procedure in place to address evaluation over time of test performance for either the Beckman Coulter AU680 or the Beckman Coulter Access 2 chemistry analyzers in use. 3. In an interview on 08/30/2021 at 0915 hours in the breakroom, the laboratory's Technical Consultant confirmed that there was no system currently in place to monitor quality of test performance over time for chemistry analyzers.
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 the laboratory's quality control records for the Beckman Coulter AU680 chemistry analyzer for August of 2022, review of patient records for the above interval and staff interview, it was determined the laboratory failed to document two levels of controls at least once a day patient samples were assayed for 3 of 29 days reviewed. Findings included: 1. Review of the laboratory's quality control records for the Beckman Coulter AU680 chemistry analyzer revealed the following days that samples were tested were missing documentation of passing two levels of controls: 08 /23/2022 08/24/2022 08/25/2022 2. Review of patient records for August 22 to August 25 of 2022 revealed the following patients' samples were tested within the interval of no QC documentation: Accession #: B222350005 Collected: 08/22/2022, 19:00 Received: 08/23/2022, 08:11 Resulted: 08/24/2022 Tested: Unable to determine. Instrument's index/date was incorrectly set to 06/30/2022. Accession #:

	B222350006 Collected: 08/22/2022, 19:00 Received:08/23/2022, 08:19 Resulted:08 /24/2022 Tested: Unable to determine. Instrument's index/date was incorrectly set to 06/30/2022. Accession #: B222350007 Collected: 08/22/2022, 19:00 Received: 08/23 /2022, 08:42 Resulted: 08/24/2022, 09:47 Tested: Unable to determine. Instrument's index/date was incorrectly set to 06/30/2022. Accession #: B222360001 Collected: 08 /23/2022, 19:00 Received: 08/24/2022, 10:13 Resulted: 08/25/2022, 07:21 Tested: Unable to determine. Instrument's index/date was incorrectly set to 06/30/2022. 3. In an interview on 08/29/2022 at 1545 hours in the breakroom, the laboratory's Testing Person number 1, after review of the data, confirmed the findings.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on review of the Laboratory Information System's (LIS) implementation records, review of random patient records for August of 2022 and staff interview it was determined the laboratory failed to document verification that instrument to LIS transmissions were being accurately and reliably conveyed to the final report destination prior to starting patient testing. Findings included: 1. Review of the Laboratory Information System's implementation records revealed no documentation that instrument to LIS transmissions were evaluated prior to starting patient testing. 2. Review of random patient records for August of 2022 revealed the patient records were printed from the LIS. These included: Accession #: B222280001 B222290002 B222350005 B222350006 B222350007 B222350008 B222360001 3. In an interview on 08/30/2022 at 1110 hours in the breakroom, the laboratory's Technical Consultant stated that the evaluation was performed but not documented. This confirmed the findings.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of the laboratory's test verification studies, review of laboratory proficiency testing (PT) records, review of laboratory's quality control records, review of patient test results and staff interview, it was determined the Laboratory Director failed to provide overall management of the laboratory as evidenced by: 1. The Laboratory Director failed to ensure the laboratory's verification studies were adequate. Refer to D6013. 2. The Laboratory Director failed to ensure the laboratory

	was enrolled in an approved PT program. Refer to D6015. 3. The Laboratory Director failed to ensure the laboratory's QC was maintained. Refer to D6020.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on review of the laboratory's verification studies for the chemistry and hematology analyzers and staff interview, it was determined the Laboratory Director failed to ensure verification studies were adequate. Refer to D5421.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing (PT) records, review of random patient test records and staff interview, it was determined the Laboratory Director failed to ensure the laboratory was enrolled in an approved PT program. Refer to D2000.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control (QC) records, review of laboratory's policies and procedures and staff interview, it was determined the Laboratory Director filed to ensure laboratory's QC was maintained. Refer to D5441 and D5447.

D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on review of the laboratory's verification studies for the hematology and chemistry analyzers and staff interview it was determined the laboratory's Technical Consultant failed to ensure verification studies were complete. Refer to D5421.
D6115	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(2) The technical supervisor is responsible for verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on review of the laboratory's establishment studies for the Bioeksen Bio-Speedy microbial detection polymerase chain reaction (PCR) panels processed on the BIORAD CFX 384 Opus analyzer, review of manufacturer's instructions for use for said panels, review of laboratory's policies and procedures and staff interview it was determined the laboratory's Technical Supervisor failed to ensure the establishment studies were complete. Refer to D5423.
D6121	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(i) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form 116, review of personnel competency assessment records and staff interview it was determined the Technical Supervisor failed to perform initial competency for 1 of 2 testing personnel employed by the facility. Findings included: 1. Review of the laboratory's submitted Form 116 revealed the laboratory employed 2 Testing Personnel. 2. Review of personnel competency assessment records revealed initial competency assessment for Testing Person number 2 was performed on 08/15/2022 by a Molecular Technologist, not the laboratory's Technical Supervisor. 3. The laboratory was asked to provide initial competency assessment for Testing Person number 2 performed by the laboratory's Technical Supervisor and no such documentation was available for review by the end of the survey. 4. In an interview on 08/29/2022 at 13:20 in the breakroom, the laboratory's Technical Supervisor, after review of the data, confirmed the findings.