Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0049978	04/21/2021
Name of Provider or Supplier	**Street Address, City, State**	
Baptist Health Medical Center Heber Springs	1800 Bypass Road, Heber Springs, AR	

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: Through observation, review of patient test logs and interview it was determined that the laboratory used expired Strep A test kits to perform Strep A screens on three of eight patient Strep A tests reviewed. Findings follow: A) In a tour of the laboratory on 4/20/21 at 02:30 PM five Osom Strep A test kits were observed in a laboratory cabinet. Two of the five Osom Strep A kits, lot # 191517 with an expiration date of 2021-3-31 labeled "current" were observed in the laboratory cabinet and one opened kit of the same lot # and expiration date was observed in the testing area. B) Review of the "Serology Patient/QC Log" for Osom Strep Lot # 191517 revealed that eight patients, identified as numbers one through eight on a patient iderntification list, had Strep A screens from that lot number . Five of the patient's test dates were prior to 2021-3-31 and three of the patients tests dates were post 2021-3-31 with patient #6 tested on 2021-04-02 and patient #'s 7 and 8 tested on 2021-04-05. C) In an interview on 4/20/21 at 02:30 PM , the laboratory staff member, identified as number four on the CMS 209 form, confirmed that the Osom Strep A kits identified above had expired and that the three patients identified above had been tested using the kits after the expiration date.
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(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: . Through a review of Blood Gas laboratory policy and procedure manual, personnel files, testing personnel authorization, proficiency testing documentation for 2020 and 2021, as well as interviews with staff, it was determined that proficiency testing samples were not tested by all personnel who routinely perform patient testing in the Blood Gas laboratory. Survey Findings follow: A. A review of the Blood Gas laboratory policy and procedure manual revealed the policy for Proficiency Testing: "Proficiency Testing (PT) will be performed on the analyzer per event. PT will be performed by the Respiratory Care Department (RCD) staff who normally perform Arterial Blood Gases (ABG) analysis." B. A review of CMS form 209 revealed the list of personnel (testing personnel #1 thru #11) who were approved, by the laboratory director, to perform Arterial Blood Gases. C. A review of Blood Gas proficiency test records for three of three events in 2020 and one event of 2021 revealed that blood gas personnel #1,#2,#3#5 and #10 (as listed on form CMS 209) had participated in proficiency testing. There was no documentation that blood gas personnel #6 and #10 (two of eleven) had performed blood gas proficiency testing in 2020 or 2021. D. In an interview, at 10:23 a.m. on 4/20/2021, Blood Gas employee #2 (as listed on the form CMS-209) confirmed that personnel who routinely run patient blood gas tests have not performed proficiency testing in 2020 or 2021.
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: . Through a review of Siemens CAC-600 coagulation analyzer user manual, lack of documentation and interview with staff, it was determined the laboratory failed to follow manufacturer's instruction in establishing normal patient mean (MNPT) for the calculation of INR results. Survey Findings follow: A. A review of the CA-600 user's manual revealed the procedure for establishing MNPT "when determining the normal reference means the laboratory should collect a minimum of 20 normal individual (10 males and 10 females) and should span the adult age range. Fresh samples are preferred but frozen platelet poor plasma may be used. Note the medication history." B. A review of the 50 samples used to establish the normal reference mean for Dade Innovin current lot #549759 revealed that the laboratory failed to document demographics of the donors. C. Upon request, the laboratory could not provide a record of the medication history, age, or gender of the donor pool used to establish the normal patient mean used to calculate INR value for Innovin lot #549759. D. In an interview on 4/21/2021 at 09:30 a.m., testing personnel #4 (as listed on CMS form 209) confirmed the laboratory did not follow manufactures instruction in determining the MNPT for Innovin lot #549759.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)

	The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Through observation, review of the manufacturer's user manual, lack of documentation and interview it was determined that the laboratory failed to monitor room temperature and humidity in one of three rooms toured in which supplies and/or instruments with temperature and humidity requirements were located and used. Findings follow: A) In a tour of the laboratory on 4/20/21 at 10:15 AM a Biomerieux Vitek 2 microbiology instrument was observed in a room separated from the main laboratory by a closable door,. B) Review of the manufacturer's user manual for the Biomerieux Vitek 2 instrument revealed a temperature requirement of 15-30 degrees C. and an operating humidity requirement of 20% - 80%. C) Upon request, the laboratory was unable to provide temperature and humidity records for the separate room identified above. D) In an interview on 4/21/21 at 01:30 PM the laboratory staff member, identified as number four on the CMS 209 form, confirmed that the Biomerieux Vitek 2 was the main microbiology instrument used by the laboratory and no temperature or humidity records were kept for the room in which the instrument was operated.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Through a review of the laboratory policies and procedures, a review of the Lyphochek Assayed Chemistry Control package inserts, a review of chemistry quality control data for July and November 2020 and March 2021, lack of documentation, and interviews with laboratory staff, it was determined the laboratory failed to have documentation of establishing statistical parameters for the Lyphochek Assayed Chemistry Controls. Survey findings include: A. Chemistry Policy and Procedure Manual included a policy for quality control using Westgard Rules, which are based on 2 Standard Deviation and 3 Standard Deviation acceptable ranges. B. The surveyor reviewed quality control data from July and November 2020 and March 2021 for

	chemistry tests performed on the Architect Chemistry Analyzer. It was determined the laboratory performs routine chemistry quality control using BioRad Unassayed Quality Control. C. The surveyor requested documentation of laboratory calculation of two and three standard deviation acceptable ranges for the BioRad Unassayed Quality Control routinely used for quality control on the Architect Chemistry Analyzer. In an interview at 1:46 p.m. on 4/20/2021, employee #3 (as listed on the form CMS-209) stated that the laboratory did not have documentation of the calculation of acceptable ranges for this control material. D. During a review of Architect Chemistry Analyzer routine chemistry quality control data for July and November 2020 and March 2021, the surveyor observed the following statement documented on 11/22/2020: "Assayed QC ran to verify performance" E. In an interview at 2:45 p.m. on 4/20/2021 laboratory employee #3 stated that the laboratory used Lyphochek Assayed Chemistry Control to verify performance when the unassayed control was questionable. She further stated that package insert ranges are used as the acceptable range on the assayed control. F. The package insert for the BioRad Lyphochek Assayed Chemistry Control states, "It is recommended that each laboratory establish its own acceptable ranges and use those provided only as guides." G. The laboratory failed to have documentation of calculating acceptable ranges on two of two control materials (BioRad Unassayed Quality Control and Lyphochek Assayed Chemistry Control) reviewed.
D5503	BACTERIOLOGY CFR(s): 493.1261(a)(2) (a) The laboratory must check the following for positive and negative reactivity using control organisms: (a)(2) Each week of use for gram stains. This STANDARD is not met as evidenced by: Through review of the laboratorys Patient Result/QC Log for gram stains, lack of documentation and interview with laboratory staff it was determined that the laboratory failed to perform weekily quality control (QC) for gram stains on one of four weeks in March 2021. Findings follow: A) Review of the laboratory's Patient Result/QC Log for gram stains in March 2021 revealed that QC from gram stains was not documented between the dates of 3/16/21 to 3/28/21. B) Review of the laboratory's Patient Result/QC log for gram stains revealed that gram stains were performed and reported on patients, identified as patients #1, #2, #3 on a separate patient identification list, on 3/24/21; grams stains were performed and reported on patient, identified as #4 on the separate patient identification list, on 3/25/21 and gram stains were performed and reported on patient, identified as #5 on the separate patient identification list, on 3/26/21. C) Upon request, the laboratory was unable to provide documentation of QC being performed for gram stains on dates between 3/16/21 and 3 /28/21. D) In an interview on 4/21/21 at 11:15 AM, the laboratory staff member identified as number four on the CMS 209 form, confirmed that gram stain QC was not performed weekly for the period of 3/16/21 to 3/28/31.