Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D0435278	05/04/2022
Name of Provider or Supplier	**Street Address, City, State**	
Hshs Good Shepherd Hospital Laboratory	200 S Cedar St, Shelbyville, IL	

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
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 review of laboratory records and interview with the technical supervisor (TS); the laboratory failed to enroll in proficiency testing (PT) for three of four General Immunology Infectious Mononucleosis Program Events for testing years 2021 and 2022. Findings Include: 1. Review of the laboratory's policy and procedure manual identified the test menu, "HSHS Good Shepherd Hospital Laboratory Test Menu May 2022", which indicated the laboratory performs Infectious Mononucleosis testing. 2. Review of American Proficiency Institute (API) proficiency testing records revealed the laboratory failed to enroll in PT for Infectious Mononucleosis (IM) testing for Event 2, 2021, Event 3, 2021 and Event 1, 2022. 3. Review of requested test volume records revealed from 05/04/2020 through 01/28/2022 55 IM tests were performed. 4. Interview with the TS, on 05/04/2022, at 12:20 pm, confirmed the laboratory failed to enroll with API for IM challenges.
D2087	ROUTINE CHEMISTRY CFR(s): 493.841(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte

	in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation, and interview with the technical supervisor (TS); the laboratory failed to achieve a satisfactory score for one of six proficiency testing (PT) events reviewed for the chemistry analyte, creatine kinase-MB isoenzyme (CK-MB) resulting in the unsatisfactory performance for event two of 2021. 1. Review of American Proficiency Institute (API) proficiency testing records revealed the laboratory received a score of zero percent for (CK-MB) on Event 2, 2021. 2. The laboratory failed to provide a documented corrective action for the event two of 2021 unsatisfactory performance for CK-MB. 3. Interview with the TS, on 05/04/2022, at 12:20 pm, confirmed the laboratory failed CK-MB PT for event two, 2021.
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 record review, lack of documentation, and interview technical supervisor (TS), the laboratory failed to establish written policies and procedures for specimen submission, handling, and referral for two of two microbiology laboratory tests submitted to reference laboratories. Findings Include: 1. Review of the laboratory's policy and procedure manual identified the test menu, "HSHS Good Shepherd Hospital Laboratory Test Menu May 2022", which indicated the laboratory performs Microbiology testing: Blood Cultures C.diff Flu RSV Strep WBC Stool Wet Prep 2. Review of requested laboratory patient (PT) reports revealed two of six patients had microbiology samples referred to reference laboratories. PT 1: Blood Culture - Date Coll: 03/09/2022 Date Rec: 03/10/2022 Testing Performed at HSHS St. John's Hospital 800 E. Carpenter, Springfield, IL PT 4: Throat/Nose Culture - Date Coll: 09 /13/2021 Date Rec: 09/14/2021 Testing Performed at HSHS St. Elizabeth's Hospital O'Fallon, IL 3. The laboratory failed to provide documented policies and procedures for two of the two microbiology specimens submitted to HSHS St. John's Hospital, 800 E. Carpenter, Springfield, IL and HSHS St. Elizabeth's Hospital O'Fallon, IL 4. Interview with the TS, on 05/04/2022, at 2:15 pm, confirmed the above findings.
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 direct observation, review of laboratory records, lack of documentation, review of the alternate blood bank (BB) refrigerator temperature log, and interview with the laboratory manager (TM), general supervisor (GS), and technical supervisor (TS); the laboratory failed to conduct calibration verifications as required for electrolytes (Sodium, Potassium, Chloride) tested on the laboratory's two Dimension EXL 200 analyzers in 2020 and 2021 (See D5439), the laboratory failed to check for positive and negative reactivity for each week of gram stain (GS) use for 328 of 328 GS slides performed for two of two years (See D5503), the laboratory failed to demonstrate performance specification comparable to those established by the manufacturer for Infectious Mononucleosis testing performed using the Poly stat Mono Test kit, affecting 55 patients' (PT) tested from 05/04/2020 to 01/28/2022 (See D5421), the laboratory failed to document results of control materials for detection of Infectious Mononucleosis antibodies for three of three test dates (See D5449), the laboratory failed to ensure an audible alarm system required to monitor proper blood and blood product storage temperature over a 24-hour period for a total of 10 days from 04/23/2022 to 05/04/2022 (See D5555).
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 laboratory records, direct observation, and interview with Technical Supervisor (TS); the laboratory failed to demonstrate performance specification comparable to those established by the manufacturer for Infectious Mononucleosis testing performed using the Poly stat Mono Test kit, affecting 55 patients' (PT) tested from 05/04/2020 to 01/28/2022. Findings Include: 1. Direct observation of laboratory testing supplies on 05/03/2022 at 10:50 am identified the Poly stat Mono Test kit used for Infectious Mononucleosis (IM) testing. 2. Review of laboratory records found no documented verification of performance for the Poly stat Mono Test kit. 3. Review of test volume records found from 05/04/20 to 01/28/22, 55 IM tests performed. 4. On 05/04/2022 at 12:38 pm, the above findings were confirmed by the TS.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as

	acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: REPEAT DEFICIENCY Based on direct observation, review of laboratory records, and interview with the laboratory manager (TM) and general supervisor (GS); the laboratory failed to conduct calibration verifications as required (at least once every six months) for electrolytes (Sodium, Potassium, Chloride) tested on the laboratory's two Dimension EXL 200 analyzers in 2020 and 2021. Findings include: 1. Direct observation of testing equipment during a tour the laboratory at 10:15 am, on 5-03-2022, identified two Siemens Dimension EXL 200 analyzers (Identified as EXL1 and EXL2). 2. Review of the laboratory procedure, "QuikLYTE (Sodium, Potassium, Chloride)", failed to identify the calibration verification procedure for electrolyte testing on the Siemens Dimension EXL 200 analyzers. 3. Review of calibration records for both Siemens Dimension EXL 200 analyzers found the laboratory failed to perform calibration verifications for sodium, potassium, and chloride. 4. Interview with the lab manager TM, on 5-04-2022, at 12:36 pm, confirmed that sodium, potassium, and chloride calibrations are two-point calibrations and no calibration verification have been performed for the electrolytes (Sodium, Potassium, Chloride) on either analyzer since 2019. 5. Review of test volume records for 2020 and 2021 revealed the laboratory performed 16,761 tests for electrolytes (Sodium, Potassium, and Chloride) on the Siemens Dimension EXL 200 analyzers during this time period. 6. Interview on 5-04-2022, at 3:39 pm, with the lab manager (TM) and GS confirmed calibration verifications were not performed for electrolytes (Sodium, Potassium, and Chloride) on the Siemens Dimension EXL 200 analyzers.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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 qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory records, patient test reports, and lack of documentation; the laboratory failed to document results of control materials for detection of infectious mononucleosis (IM) antibodies for three of three test dates. A total of 55

	patients were tested for the dates of 05/04/2020 through 01/28/2022. Findings Include: 1. Three patient results were reviewed for mononucleosis detection: PT 3 : Test date - 03/10/2022 PT 4: Test date - 09/13/2021 PT 5: Test date - 05/13/2020 2. Review of laboratory quality control (QC) documentation revealed an IM QC log sheet marked: External Quality Control Log Sheet Manufacturer: Meridian Dates of Negative QC and Positive QC: 03/01/19 04/30/19 12/20/19 02/04/20 08/09/20 12/02/21 3. The laboratory failed to provide IM QC documentation for three of three reported patients' test dates.
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: Based on direct observation, lack of documentation, and interview with Laboratory Services Director (LSD); the laboratory failed to check for positive and negative reactivity for each week of gram stain (GS) use for 328 of 328 GS slides performed for two of two years. Years 2020 (155 GS) and 2021 (173 GS). Findings Include: 1. On 5/4/2022 at 12:45 p.m., direct observation and tour of the laboratory revealed GS station and solutions. 2. Review of requested laboratory tests volumes for years 2020 and 2021 revealed a total of 328 GS slides performed. 3. The laboratory failed to provide weekly documented GS quality control (QC) records for years 2020 and 2021. 4. On 5/4/2022 at 2:22 p.m., LSD confirmed the above findings by stating the laboratory does not document GS QC.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on direct observation, review of the alternate blood bank (BB) refrigerator temperature log, and interview with Technical Supervisor (TS); the laboratory failed to ensure an audible alarm system required to monitor proper blood and blood product storage temperature over a 24-hour period for a total of 10 days from 04/23/2022 to 05 /04/2022. Findings include: 1. On 05/03/2022, at 10:15 am, tour of the Blood Bank (BB) section of the laboratory and direct observation revealed all blood products removed from the dedicated BB refrigerator and placed in an alternate refrigerator that failed to have an audible alarm. 2. On 05/03/2022, at 10:15 am, TS confirmed the BB products were moved to an alternate refrigerator on 04/23/2022.