Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D2170189	09/10/2020
Name of Provider or Supplier	**Street Address, City, State**	
Mercy Springdale Hod	4600 Mercy Lane, Springdale, 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Through review of proficiency testing attestation forms and interview it was determined that the laboratory director or designee failed to attest that the proficiency testing was performed in the same manner as patient testing in six of six (6) events reviewed. Survey findings follow: A) Review of proficiency testing attestation documents for API Chemistry Core 2020 1st event, 2nd event, 3rd event, API Hematology/Coagulation 2020 1st event, 2nd event, and API Chemistry Miscellaneous 2020 1st event revealed that they were not signed by the laboratory director or designee. B) In an interview on 9/9/20 at approximately 10:00 AM the laboratory staff member identified as number four on the CMS 209 form confirmed that the attestation forms identified above were not signed by the laboratory director or designee.
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, lack of documentation and interview it was determined that the laboratory failed to document room temperature in one of two rooms surveyed in which supplies with storage temperature requirements were located. Findings follow: A) During a tour of the laboratory on 9/10/20 at approximately 01:30 PM, the surveyor observed 13 BD Lithium Heparin 4.5 ml. blood collection tubes lot# 0044189 expiration date 2021-02-03, 3 BD Lithium Heparin 15 ml. blood collection tubes lot# 01900258 expiration date 2021-04-30, and 10 BD EDTA blood collection tubes lot# 9184929 expiration date 2020-11-30 in a separate phlebotomy room separated from the laboratory by a closable door. B) Upon request the laboratory was unable to provide documentation of temperature records for the room identified above. C) In an interview on 9/10/20 at approximately 02:00 PM, the laboratory staff member identified as number four on the CMS 209 form confirmed that the laboratory failed to measure and document temperature in the room identified above.
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: Through review of quality control documentation for prothrombin times (PT) and partial thromboplastin times (APTT) for November 2019, March 2020, July 2020, lack of documentation and interview it was determined that the laboratory failed to have a method for evaluating changes in procedure performance over time. Findings follow: A) When asked for the QC control summaries for PT and APTT testing for November 2019, March 2020 and July 2020 the laboratory provided daily QC results only. B) Upon request, the laboratory was unable to provide Levy-Jennings graphs or other documentation of monitoring QC performance over time. C) In an interview on 9/9/20 at approximately 01:30 PM, the laboratory staff member identified as number four on the CMS 209 form stated that Levy-Jennings graphs from the "Beaker" information system were unusable due to the reports being "skewed and invalid", that the laboratory had been unable to submit QC results to the "Stago Clarity" peer review system and there was no system currently in use to provide information for changes in QC performance over time for PT and APTT testing.
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 review of the laboratory's Policy and Procedure for "Coagulation Testing STA-Satellite" document ID# 5D-Coag-9001, quality control (QC) results for Prothrombin Time (PT) and Activated Partial Thromboplastin Time (APTT) for June 2020, QC summary reports from the Laboratory "Beaker" information system and interview it was determined that the laboratory failed to establish correct acceptable ranges for PT and APTT testing. This could affect all PT and APTT testing performed at the laboratory. Findings follow: A) The policy and procedure for Coagulation Testing on the STA-Satellite document # 5D-Coag-9001 states "all QC must follow Westergren Rules and fall within a 2 Standard Deviation (SD) range to be acceptable". B) Review of the QC summary reports of actual SD for coagulation testing for lot# 255798 for June 2020 revealed the following actual SD, and acceptable range if the laboratory policy and procedure was followed: * Normal PT SD 0.4, acceptable range (13.2 - 14.8) * Abnormal PT SD 1.0, acceptable range (29.9 -33.9) * Normal APTT SD 0.7, acceptable range (33.1-35.9) * Abnormal APTT SD 2.7, acceptable range (78.3-89.1) C) Review of QC reports for control lot# 255798 for PT and APTT testing in June 2020 revealed the following was adopted by the laboratory as their target and acceptable ranges: * Normal PT Target 14, acceptable range (12.5 - 15.5), 1 SD equals 0.8 , This represents an acceptable range of plus /minus 4SD * Abnormal PT Target 31.9, acceptable range (26.4 - 37.4), 1 SD equals 2.8, This represents an acceptable range of plud/minus 5.6 SD * Normal APTT Target 34.5, acceptable range (29 - 40). 1 SD equals 2.8, This represents an acceptable range of plus/minus 8 SD * Abnormal APTT Target 83.7, acceptable range (76.7 - 90.7), 1 SD equals 3.5, This represents an acceptable range of plus/minus 2.6 SD D) In an interview on 9/9/20 at approximately 03:30 PM, the laboratory staff member identified as number four on the CMS 209 form confirmed that the acceptable ranges in use for PT and APTT QC were not correctly established and did not comply with the laboratory's QC policy and procedure.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Through review of Levy-Jennings QC charts for chemistry testing for January 2020, patient result reports, and interview it was determined that patient testing was performed and reported in nine (9) of twelve (12) instances when QC was

	unacceptable. Findings follow: A) Review of Levy-Jennings QC chart revealed that level 1 QC lot# 67600 for Troponin was unacceptable greater than three (3) standard deviations (SD) from the target on 1/9/20, 1/14/20, and 1/28/20 and troponin tests were performed and reported on patient identified as number 1 on a separate patient identification worksheet on 1/9/20, reported on patient identified as number 2 on a separate patient identification worksheet on 1/28/20. B) Review of Levy-Jennings QC chart revealed that level 2 QC lot# 45810 for Lipase was unacceptable greater than three (3) standard deviations (SD) from the target on 1/8/20 and 1/11/20 and Lipase tests were performed and reported on patients identified as number 3,4,5,6, on a separate patient identification worksheet on 1/11/20. C) Review of Levy-Jennings QC chart revealed that level 1 QC lot# 45810 for Albumin was unacceptable greater than three (3) standard deviations (SD) from the target on 1/20/20, 1/23/20, 1/27/20 and 1 /29/20 and Albumin tests were performed and reported on patients identified as numbers 7 through 12 on a separate patient identification worksheet on 1/20/20, reported on patients identified as numbers 14 through 22 on a separate patient identification worksheet on 1/23/20, patients identified as numbers 16 and 23 through 26 on 1/27/20 and performed and reported on patients identified as numbers 27 through 29 on 1/29/20. D) Review of Levy-Jennings QC chart revealed that level 1 Immunoassay Plus QC lot# 40980 for HCG was unacceptable greater than three (3) standard deviations (SD) from the target on 1/18/20 and HCG tests were performed and reported on patients identified as number 30, 31 on a separate patient identification worksheet on that day. E) In an interview on 9/10/20 at approximately 02:30 PM, the laboratory staff member identified as number two on the CMS 209 form, confirmed that QC performance failed acceptable limits on the days identified above.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Through review of documents associated with API 2020 Hematology/Coagulation 2020 proficiency testing and interview it was determined that corrective action was not effective in two of two events reviewed. Findings follow: A) Review of the result evaluation of API Hematology/Coagulation 1st event revealed unsuccessful performance for # Basophil and # Eosinophil for specimens XE-02 and XE-04. B) Review of the attestation form for API Hematology/Coagulation 2020 1st event that specimen XE-02 was performed by the laboratory staff member identified as number nine on the CMS 209 form and specimen XE-04 was performed by laboratory staff member identified as number 8 on the CMS 209 form. C) Review of the corrective action form for API Hematology/Coagulation 2020 revealed that the failure was attributed to a mixing error and the corrective action was that personnel were trained on warming and mixing of proficiency testing samples. D) Review of the result evaluation of API Hematology/Coagulation 2nd event revealed unsuccessful performance for # Basophil and # Eosinophil for specimens XE-07 and XE-07. E) Review of the attestation form for API Hematology/Coagulation 2020 2nd event that specimen XE-06 was performed by the laboratory staff member identified as number

	nine on the CMS 209 form and specimen XE-07 was performed by laboratory staff member identified as number 8 on the CMS 209 form. F) Review of the corrective action form for API Hematology/Coagulation 2020 revealed that the failure on the 2nd event was attributed to a mixing error and the corrective action was that personnel were trained on warming and mixing of proficiency testing samples. G) In an interview on 9/9/20 at approximately 04:00 PM the laboratory personnel identified as number two on the CMS 209 form confirmed that the corrective action for the unsuccessful results on the proficiency testing events identified above was not effective.