Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D0453069	09/22/2021
Name of Provider or Supplier	**Street Address, City, State**	
Decatur Health System Inc	810 W Columbia St, Oberlin, KS	

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: Based on a review of proficiency testing (PT) from the provider American Proficiency Institute (API) performed 2/22/19 to 9/22/21 and interview with General Supervisor #1 (GS#1) revealed that the laboratory director (LD) or designee failed to attest on 6 of 28 events that proficiency testing samples were handled in the same manner as patient samples. 1. Review of the attestation page for PT from API revealed the LD or designee signature was not present on: a. API 2020 Chemistry Core 3rd Event b. API 2020 Hematology/Coagulation 1st Event c. API 2020 Microbiology 3rd Event d. API 2020 Immunology/Immunohematology 2nd Event e. API 2020 Immunology /Immunohematology 3rd Event f. API 2020 Chemistry Miscellaneous 2nd Event 2. Interview with GS #1 on 9/22/21 at 12:30 p.m. confirmed, the LD or designee failed to attest on 6 of 28 events that proficiency testing samples were handled in the same manner as patient samples.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).

	This STANDARD is not met as evidenced by: Based on review of the laboratory's 2019, 2020, and 2021 to date of survey API PT documentation and interview with GS#1, the laboratory failed to verify the accuracy of hematology analytes that were assigned a ungraded proficiency testing score for one of seven events. Findings: 1. Review of the laboratory's 2019, 2020, and 2021 to date of survey API PT documentation for hematology analytes found the following ungraded results: 2020 Hematology/Coagulation 1st Event a. Blood Cell Identification samples ECI-01, 02, 03, 04 and 05 b. Fecal Leukocytes sample FW-01 2. Review of the laboratory's API PT Performance Review and Corrective Action forms failed to find any documentation demonstrating a self-assessment or self-grade of the ungraded samples. 3. Interview with GS#1 on 9/22/21 at 12:30 a.m. confirmed, the laboratory failed to verify the accuracy of hematology analytes that were assigned a ungraded proficiency testing score for one of seven events..
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of the laboratory's 2019, 2020, and 2021 to date of survey API PT documentation and interview with GS#1, the laboratory failed to verify the accuracy of hematology analytes that were assigned an unacceptable proficiency testing score for one of seven events. Findings: 1. Review of the laboratory's 2019, 2020, and 2021 to date of survey API PT Performance Review and Corrective Action forms for hematology analytes found the following unacceptable results: 2020 Hematology/ Coagulation 1st Event-Blood Cell Indentification BCI-03 2. No documentation of evaluation, investigation or corrective action was present for the unacceptable result. 3. Interview with GS#1 on 9/22/21 at 12:30 a.m. confirmed, the laboratory failed to verify the accuracy of hematology analytes that were assigned an unacceptable proficiency testing score for one of seven events.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of the laboratory's 2019, 2020, and 2021 to date of survey API PT documentation, the lack of corrective action (CA) documentation, and interview with GS#1, the laboratory failed to utilize an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the general laboratory systems. Findings: 1. Review of the API PT Performance Review and Corrective Action documents for 2019 Chemistry Miscellaneous 1st Event showed results were not submitted prior to the reporting deadline. No corrective action listed to prevent failure to submit timely. 2. Review of API PT Performance Review and Corrective Action documents for 2020 Chemistry Core 1st Event showed 2 unacceptable test results:

	BNP sample CM-05 and Myoglobin sample CM-04. Documentation did not include an investigation as to the cause of the failure and no corrective action was listed. 3. Review of API PT Performance Review and Corrective Action documents for 2020 Chemistry Core 2nd Event showed: a. Unacceptable test results due to specimen misidentification for CM-07 and CM-08. No corrective action was listed. b. Unacceptable results were listed for ALC-09. Documentation did not include an investigation as to the cause of the failure and no corrective action was listed. 4. Review of API PT Performance Review and Corrective Action documents for 2020 Chemistry Core 3rd Event showed unacceptable test results for pCO2 on samples BG-12 and BG-13. No corrective action was listed. 5. Review of the API PT Performance Review and Corrective Action documents for 2020 Immunology/Immunohematology 3rd Event showed results were not submitted prior to the reporting deadline. No corrective action listed to prevent failure to submit timely. 6. Interview with GS #1 on 9/22/21 at 12:30 p.m. confirmed, the laboratory failed to utilize an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the general laboratory systems.
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 the review of 1/28/21 to 9/21/21 patient test records and quality control (QC) records revealed that the laboratory failed to perform a positive and negative control material each day of patient testing on the Cepheid GeneXpert SARS-CoV-2 /Flu/RSV Findings: 1. Review of patient testing logs and QC data revealed the laboratory failed to perform QC testing on each day of use on the following dates of the year 2021: 1/28, 1/30, 2/1 -2/5, 2/7, 2/9-2/12, 2/15, 2/16, 2/19, 2/21, 2/22, 2/24-2 /26, 3/1, 3/6-3/9, 3/11, 3/12, 3/15-3/17, 3/19, 3/20, 3/22, 3/24, 3/25, 3/29-3/31, 4/2, 4 /3, 4/5-4/8, 4/10, 4/12-4/20, 4/27-4/29, 5/3, 5/6-5/8, 5/10, 5/14, 5/18, 6/6-6/8, 6/15, 6 /18, 6/21, 6/25, 6/26, 7/1, 4/6, 7/8-7/10, 7/12-7/15, 7/17, 7/19, 7/20, 7/22-7/24, 7/26-7 /30, 8/2-8/7, 8/9-8/14, 8/17, 8/19-8/21, 8/23-8/25, 8/27-9/6, 9/8-9/10, 9/13-9/19, 9/21 for a total of 267 patient tests resulted. 2. No IQCP had been authorized to enable the laboratory to reduce the frequency of QC. 3. Interview with GS#1 on 9/22/21 at 4 p.m. confirmed, the laboratory failed to perform a positive and negative control material each day of patient testing on the Cepheid GeneXpert SARS-CoV-2/Flu/RSV.
D5451	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(iii)(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-- Test procedures producing graded or titered results include a negative control material and a control material with graded or titered reactivity, respectively; 493.1256 (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on the review of "Quality Control for Blood Band reagents" procedure and quality control (QC) records from 8/1/21 to date of survey revealed the laboratory failed to perform QC each day of patient testing for the immunohematology test procedures that produce graded or titered results and include a negative control. Findings: 1. Review of the "Quality Control for Blood Band reagents" procedure revealed only one expected negative reaction result for the Rh negative control. All other reagent testing expected results are graded positive reactions. 2. Review of the immunohematology records, which are recorded on the patient test log revealed the following immunohematology reagent QC testing does not include a negative result:. anti-A, anti-B, anti-D, anti-D (1:50), A cells, B cells, Search Cyte I, Search Cyte II, Combs Check Cells, Anti-IgG. 3. Interview with the GS#1 on 9/22/21 at 1:40 p.m. confirmed, the laboratory failed to perform QC each day of patient testing for the immunohematology test procedures that produce graded or titered results and include a negative control.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that 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 the review of instrument verification records and interview with GS#1, the laboratory director failed to ensure the establishment of acceptable levels of analytical performance of the Cepheid GeneXpert SARS-CoV-2/Flu/RSV and the Sysmex XN-450 hematology analyer before use in patient testing. 1. Review of instrument verification records for the Cepheid GeneXpert SARS-CoV-2/Flu/RSV performed 12 /22/2020 to 12/31/21 and placed into use for patient testing on 1/5/21, revealed no approval documentation from the laboratory director or designee. 2. Review of insturment verification records for the Sysmex XN-450, S/N 11897 hematology analyzer for White Blood Cell Count, Red Blood Cell Count, Hemoglobin, Hematocrit, Platelet Count, and White Blood Cell Differential was performed in March 2019 and placed into use for patient testing in early April 2019 (exact date patient testing began was not made available at the time of survey) revealed no approval documentation from the laboratory director or designee. 3. Interview with the GS#1 9/22/21 at 4:10 p.m. confirmed, the laboratory director failed to ensure the establishment of acceptable levels of analytical performance of the Cepheid GeneXpert SARS-CoV-2/Flu/RSV and the Sysmex XN-450 hematology analyer before use in patient testing.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by:

	Based on review of API PT Performance Review and Corrective Action forms for 2020 and interview with GS#1, the laboratory director failed to ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance. Findings: 1. Review of API PT Performance Review and Corrective Action for 2020 Immunology/Immunohematology 2nd Event showed no signature of the laboratory director, who is also the technical supervisor of immunohematology and the only qualified individual at this laboratory to evaluate the laboratory's immunohematology performance. 2. Review of API PT Performance Review and Corrective Action for 2020 Immunology/Immunohematology 3rd Event showed no signature of the laboratory director, who is also the technical supervisor of immunohematology and the only qualified individual at this laboratory to evaluate the laboratory's immunohematology performance. This event was not filed within the submission period and required a self evaluation to be performed. 3. Interview with GS#1 on 9/22/21 at 12:30 p.m. confirmed, the laboratory director failed to ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on the review of the Xpert SARS-CoV-2/Flu/RSV procedure, hematology procedure manual, and interview, the laboratory director failed to ensure an approved procedure for the Xpert SARS-CoV-2/Flu/RSV test and the Sysmex XN-450 hematology analyzer for White Blood Cell Count, Red Blood Cell Count, Hemoglobin, Hematocrit, Platelet Count, and White Blood Cell Differential was signed by the laboratory director before used for patient testing. Findings: 1. Review of the procedure "Xpert SARS-CoV-2/Flu/RSV" found that it had not been signed by the laboratory director. 2. Request was made for the procedure for Complete Blood Count (CBC) testing done on the Sysmex XN-450 hematology analyzer for White Blood Cell Count, Red Blood Cell Count, Hemoglobin, Hematocrit, Platelet Count, and White Blood Cell Differential. No procedure was made available at the time of survey. The only procedure for CBC testing was for a hematology analyzer no longer in use at this laboratory. 3. The Xpert SARS-CoV-2/Flu/RSV test has been performed on 267 patients without an approved procedure from 1/28/21 to date of survey. 4. The Sysmex XN-450 hematology analyzer for White Blood Cell Count, Red Blood Cell Count, Hemoglobin, Hematocrit, Platelet Count, and White Blood Cell Differential testing has been performed on 5,697 patients without an approved procedure from early April 2019 to date of survey.