Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0383057	04/13/2023
Name of Provider or Supplier	**Street Address, City, State**	
Dallas County Hospital Family Medicine Panora	319 East Main Street, Panora, IA	

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
D5024	HEMATOLOGY CFR(s): 493.1215 If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493. 1281 through 493.1299. This CONDITION is not met as evidenced by: Based on review of laboratory procedure manual, hematology quality control records, Yearly Temperature/Humidity Chart, Sysmex maintenance records and confirmed by testing personnel #1 (refer to Laboratory Personnel Report), the laboratory failed to follow the Quality Control Policy as specified in D5401; document daily humidity levels as specified in D5413; document daily maintenance as specified in D5429; perform quality controls as specified in D5447, document corrective action when quality control results fail to meet the laboratory's established criteria for acceptability as specified in D5783; and establish quality assessment policies and procedures which identify laboratory problems as specified in D5791.
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 the laboratory procedure manual and hematology quality control (QC) records and confirmed by laboratory personnel identifier #1 (refer to the

	Laboratory Personnel Report) at approximately 1:30 pm on 4/13/2023, the laboratory failed to follow the Quality Control Policy for performing hematology QC each day of patient testing for ten out of 18 days from 1/1/2023 - 2/28/2023. The findings include: 1. The Quality Control Policy under the section titled "Specialty/Subspecialty Quality Control Requirements" states "Hematology Sysmex XN430 - Analyze 3 levels of QC material after performing daily start up and before performing patient testing." 2. The laboratory performed patient testing on the Sysmex XN430 on the following dates: *1 /04/2023 - performed testing on 3 patients *1/10/2023 - performed testing on 1 patient *1/11/2023 - performed testing on 2 patients *1/12/2023 - performed testing on 1 patient *1/16/2023 - performed testing on 2 patients *1/17/2023 - performed testing on 3 patients *1/18/2023 - performed testing on 5 patients *1/25/2023 - performed testing on 3 patients *1/26/2023 - performed testing on 1 patient *1/30/2023 - performed testing on 3 patients 3. At the time of the survey, the laboratory did not perform three levels of QC on the above listed dates.
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: Based on review of the laboratory procedure manual and Yearly Temperature /Humidity Chart and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 1:30 pm on 4/13/2023, the laboratory failed to document the laboratory humidity levels for 26 out of 29 days from 1/1/2023 - 2/28/2023. The findings include: 1. The Temperature Dependent Equipment Policy stated, "Acceptable humidity ranges should be lowest and highest acceptable temperature for the storage or analysis of the specimens, instruments or reagents being stored. General acceptable ranges are: Room humidity 15 - 75%." 2. Review of the Yearly Temperature/Humidity Chart revealed the laboratory failed to document the humidity levels on the following dates in 2023: 1/4, 1/5, 1/10, 1/11, 1/12, 1/16, 1/17, 1 /18, 1/19, 1/23, 1/24, 1/25, 1/26, 1/30, 1/31, 2/1, 2/6, 2/7, 2/8, 2/9, 2/13, 2/15, 2/20, 2 /21, 2/22, and 2/27.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of Sysmex maintenance records and confirmed by laboratory personnel identifier #1 (refer to Laboratory Personnel Report) at approximately 1:30 pm on 04/13/2023, the laboratory failed to perform and document daily maintenance

	on the Sysmex hematology analyzer for two out of 29 days of patient testing from 1/1 /2023 - 2/28/2023. The findings include: 1. The Sysmex maintenance log stated the laboratory must daily perform the following: *Perform Start-up *Check/Empty Waste Container *Perform Quality Control (QC) *Review QC *Check Background Count *Perform Shutdown 2. At the time of the survey, the laboratory did not document daily maintenance for the Sysmex analyzer on 1/19/2023 and 1/31/2023.
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 procedure manual and hematology quality control (QC) records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 1:30 pm on 4/13/2023, the laboratory failed to perform three levels of hematology QC each day of patient testing for ten out of 18 days from 1/1/2023 - 2/28/2023. Refer to D5401 for findings.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of the hematology quality control (QC) records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 1:30 pm on 4/13/2023, the laboratory failed to document corrective action when QC failed to meet the laboratory's established criteria for acceptability for one out of 18 days from 1/1/2023 - 2/28/2023. The findings include: 1. On 2/10/2023, the laboratory performed three levels of hematology QC. 2. Each of the three levels of QC on 2/10/23 had an SM error flag. 3. The quality control log stated that an SM flag is a system managed data error and has automatically been excluded from QC calculations. 4. At the time of the survey, the laboratory did not document corrective action for the SM flag on 2/10/2023.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of Sysmex maintenance logs, hematology quality control (QC) records,Yearly Temperature/Humidity Chart and the Technical Consultant Monthly Report and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report), at approximately 1:30 pm on 4/13/2023, the laboratory failed to establish quality assessment policies and procedures which identified problems associated with documenting maintenance, performing QC, and documenting humidity levels from 1/1/2023 - 2/28/2023. The findings include: 1. The Technical Consultant Monthly Report dated 2/10/2023 stated, "Maintenance was properly documented for instruments in use." 1a. The laboratory did not document maintenance for two out of 29 days from 1/1/2023 - 2/28/2023. Refer to D5429 for findings. 1b. The laboratory documented they performed Sysmex maintenance on 2/29/2023, which is a possible date in 2023. 1c. The daily Sysmex maintenance log includes "Perform QC.". The laboratory documented maintenance being completed, including QC being performed, on 1/10/23, 1/11/23, 1/12/23, 1/16/23, 1/17/23, 1/18/23, 1/25/23 and 1/26 /23. The laboratory did not perform QC on these dates. Refer to D5401 for findings. 2. The Technical Consultant Monthly Report dated 2/10/2023 stated, "Three levels of control were run each day testing was performed and were all within the 2 SD established ranges for the given level. Current lot expires 2/28/2023." 2a. The laboratory did not perform QC 10 out of 18 days of patient testing from 1/1/2023 - 2 /28/2023, refer to D5401. 2b. The laboratory did not documented corrective action when the laboratory received a QC error flag on 2/10/23. Refer to D5783 for findings. 3. The Technical Consultant Monthly Report dated 2/10/2023 stated, "Temperatures are monitored by Digitrack. Reviewed 2/10/2023, all within range." The laboratory did not document humidity levels for 27 out of 29 days from 1/1/2023 - 2/28/2023. Refer to D5413 for 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 laboratory procedure manual, hematology quality control records, Yearly Temperature/Humidity Chart, Sysmex maintenance records and confirmed by testing personnel #1 (refer to Laboratory Personnel Report), the director failed to ensure the laboratory maintained an acceptable quality control program as specified in D6020; ensure the laboratory established a quality assessment program to identify failures in quality as specified in D6022; and ensure the laboratory documented corrective action when quality controls failed to meet the laboratory's established criteria for acceptability as specified in D6024.
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 procedure manual and hematology quality control (QC) records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 1:30 pm on 4/13/2023, the laboratory director failed to ensure the laboratory performed three levels of hematology QC each day of patient testing for ten out of 18 days from 1/1/2023 - 2/28/2023. Refer to D5401 for findings.
D6022	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 and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of Sysmex maintenance logs, hematology quality control (QC) records,Yearly Temperature/Humidity Chart and the Technical Consultant Monthly Report and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report), at approximately 1:30 pm on 4/13/2023, the laboratory director failed to ensure the laboratory established quality assessment policies and procedures which identified problems associated with documenting maintenance, performing QC, and documenting humidity levels from 1/1/2023 - 2/28/2023. Refer to D5791 for findings.
D6024	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) 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)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, This STANDARD is not met as evidenced by: Based on review of the hematology quality control (QC) records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 1:30 pm on 4/13/2023, the laboratory director failed to ensure the laboratory documented corrective action when QC failed to meet the laboratory's

	established criteria for acceptability for one out of 18 days from 1/1/2023 - 2/28/2023. Refer to D5783 for findings.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on review of laboratory procedure manual, hematology quality control records, Yearly Temperature/Humidity Chart, Sysmex maintenance records and confirmed by testing personnel #1 (refer to Laboratory Personnel Report), the technical consultant failed to establish and maintain quality control procedures as specified in D6042 and ensure corrective action is taken when quality control results did not meet the laboratory's established criteria for acceptability as specified in D6043.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual and hematology quality control (QC) records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 1:30 pm on 4/13/2023, the technical consultant failed to ensure the laboratory followed the Quality Control Policy for performing hematology QC each day of patient testing for ten out of 18 days from 1/1 /2023 - 2/28/2023. Refer to D5401 for findings.
D6043	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(5) (b) The technical consultant is responsible for-- (b)(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications; This STANDARD is not met as evidenced by: Based on review of the hematology quality control (QC) records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 1:30 pm on 4/13/2023, the technical consultant failed to ensure the laboratory documented corrective action when QC failed to meet the laboratory's established criteria for acceptability for one out of 18 days from 1/1/2023 - 2/28/2023. Refer to D5783 for findings.