Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D2087348	(X3) Date Survey Completed 09/20/2019
Name of Provider or Supplier University Of Iowa Health Care	**Street Address, City, State** 2769 Heartland Drive, Suite 100, Coralville, 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
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: A. Based on review of Sysmex XP-300 hematology analyzer maintenance records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 10:30 am on 09/20/2019, the laboratory failed to document daily maintenance as defined by the manufacturer for one out of three days of patient testing (03/30/2019) reviewed in March 2018. The findings include: 1. Patient A had a complete blood count (CBC) performed on 03/30/2019. 2. Patient B had a CBC performed on 03/07/2019. 3. Patient C had a CBC performed on 03/29/2019. 4. The XP-300 maintenance log indicated that the following tasks are to be performed and documented daily: *Perform Shutdown *Verify Background *Verify Vacuum /Pressure *Check Trap Chamber *Perform Quality Control 5. Review of the XP-300 maintenance log revealed that the laboratory documented each daily maintenance task on 03/07/2019 and 03/29/2019. 6. At the time of the survey, personnel identifier #1 confirmed that the laboratory did not document daily maintenance on 03/30/2019. B. Based on review of Sysmex XP-300 hematology analyzer maintenance records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 10:30 am on 09/20/2019, the laboratory failed to document weekly maintenance as defined by the manufacturer for two out of four weeks (03/20 /2019 and 03/27/2019) of patient testing in March 2018. The findings include: 1. The XP-300 maintenance log indicated that the following task is to be performed and documented weekly: Clean SRV Tray. 2. Review of the XP-300 maintenance log

	revealed that the laboratory documented weekly maintenance on 03/06/2019 and 03/13/2019. 3. At the time of the survey, personnel identifier #1 confirmed that the laboratory did not document weekly maintenance on 03/20/2019 and 03/27/2019.
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: A. Based on review of Sysmex XP-300 complete blood count (CBC) analyzer printouts, patient test reports, quality assessment records, and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 10:00 am on 09/20/2019, the laboratory failed to establish a written quality assessment policy to monitor, assess and correct problems related to inconsistently entering a positive patient identifier into the Sysmex XP-300 hematology analyzer for three out of three patients (patient identifiers A, B, and C) having CBC testing performed in March 2019. The findings include: 1. When performing a CBC, the laboratory inputs a sample ID into the Sysmex XP-300 analyzer to identify the current sample being analyzed. Once analysis is complete, the instrument prints a report of the results and laboratory personnel handwrite the patient's full name and date of birth (DOB) on it. 2. Patient A had a CBC performed on 03/30/2019. The laboratory entered 04-23-10 as the sample ID. Upon completion, the laboratory wrote Patient A's name and DOB on the printout. 3. Patient B had a CBC performed on 03/07/2019. The laboratory entered BH as the sample ID. Upon completion, the laboratory wrote Patient B's name and DOB on the printout. 4. Patient C had a CBC performed on 03/29/2019. The laboratory entered 1 as the sample ID. Upon completion, the laboratory wrote Patient C's name and DOB on the printout. 5. Quality assessment activities performed in March 2019 did not identify problems related to laboratory personnel inconsistently entering a positive patient identifier into the Sysmex XP-300 hematology analyzer. B. Based on review of Sysmex XP-300 complete blood count (CBC) analyzer printouts, patient test reports, quality assessment records, and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 10:00 am on 09/20/2019, the laboratory failed to establish a written quality assessment policy to monitor, assess and correct problems related to incorrectly writing two positive patient identifiers on Sysmex XP-300 analyzer printouts for one out of three patients (patient identifier A) having CBC testing performed in March 2019. The findings include: 1. When performing a CBC, the laboratory inputs a sample ID into the Sysmex XP-300 analyzer to identify the current sample being analyzed. Once analysis is complete, the instrument prints a report of the results and laboratory personnel handwrite the patient's full name and date of birth (DOB) on it. 2. Patient A had a CBC performed on 03/30/2019. Upon sample completion, the laboratory wrote Patient A's name and DOB of 04/23/10 on the Sysmex XP-300 result printout. 3. Review of Patient A's electronic medical record (EMR) indicated the laboratory had written the patient's name correctly. The EMR had Patient A's DOB as 04/23/2018. 4. At the time of the survey, personnel identifier #1 confirmed that Patient A's DOB had been incorrectly written on the Sysmex XP-300 result printout. 5. Quality assessment activities performed in March 2019 did not identify problems related to laboratory personnel writing patient DOBs incorrectly on Sysmex XP-300 result printouts.

D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on review of Sysmex XP-300 instrument printouts, patient test reports, the laboratory's test resulting procedure,quality assessment records, and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 10:00 am on 09/20/2019, the laboratory failed to have a system in place to monitor, assess, and correct problems associated with inconsistently reporting complete blood count (CBC) test results and units of measure in the patient's electronic medical record (EMR) for three out of three patients (Patients A, B, and C) having CBC testing in March 2019. The findings include: 1. Patient A had a CBC performed on 03/30/2019. Comparison of the Sysmex XP-300 instrument printout and Patient A's EMR record indicated the laboratory entered correct test results for all analytes and/or indices, but incorrect, inconsistent, or missing units of measure for the following (see attachment A for correct units of measure and Patient A's EMR results): *White blood count (WBC) *Lymphocyte count *Mean corpuscular hemoglobin (MCH) *Mean corpuscular hemoglobin concentration (MCHC) *Platelet histogram *Granulocyte count *Monocyte count *Monocytes per 100 leukocytes *Red cell distribution width, standard deviation (RDW-SD) *Red cell distribution width, coefficient of variation (RDW-CV) *Mean platelet volume (MPV) 2. Patient B had a CBC performed on 03/07/2019. Comparison of the Sysmex XP-300 instrument printout and Patient B's EMR record indicated the laboratory entered correct test results for all analytes and/or indices, but incorrect, inconsistent, or missing units of measure for the following (see attachment B for correct units of measure and Patient B's EMR results): *WBC *Lymphocyte count *Monocyte count *Granulocyte count *MCH *MCHC *Platelet histogram *RDW-SD *RDW-CV 3. Patient C had a CBC performed on 03/29/2019. Comparison of the Sysmex XP-300 instrument printout and Patient C's EMR record indicated the laboratory entered correct test results for all analytes and/or indices, but incorrect, inconsistent, or missing units of measure for the following (see attachment C for correct units of measure and Patient C's EMR results): *WBC *Lymphocyte count *MCH *MCHC *Platelet histogram *Monocyte count *Granulocyte count *RDW-SD *RDW-CV 4. The laboratory's procedure, "Resulting In-House Labs," instructs personnel to do the following: 1- Select correct patient 2- Click on the NOTES tab 3- Click on the FORMS section 4- Use CLINIC TEAM or STANDARD CLINIC TEAM 5- Click on LABS/TESTS 6- Select the correct tab 7- Type in result from instrument or instrument print-off 8- Click save 5. CBC test results and units of measure appeared differently in the EMR for each of the patients A, B, and C. Refer to attachments A, B, and C. 6. Quality assessment activities performed in March 2019 did not identify problems related to laboratory personnel inconsistently reporting CBC test results and units of measure in patient EMR records.