Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D2087348	11/11/2021
Name of Provider or Supplier	**Street Address, City, State**	
University Of Iowa Health Care	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
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 procedures, personnel and proficiency testing records and lack of quality assessment records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report); the laboratory director failed to meet the responsibilities for the overall operation and administration of the laboratory, including: to ensure proficiency testing samples are tested as required under subpart H refer to D6016; to ensure quality assessment programs are established and maintained refer to D6021; to ensure prior to testing patients' specimens, all personnel have documented training refer to D6029; and to ensure all testing personnel have documented competency refer to D6030.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by:

	Based on review of proficiency testing (PT) records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 8: 45 am on 11/11/2021; the laboratory director failed to ensure that the testing personnel and laboratory director attested to the routine integration of PT samples into the patient workload for three out of three proficiency testing events (2020 events 1 and 2, and 2021 event 1) from 1/1/2020 - 11/11/2021. The findings include: 1. For 2020 event 1, the laboratory director failed to sign the PT attestation statement. 2. For 2020 event 2, the laboratory director and testing personnel failed to sign the PT attestation statement. 3. For 2021 event 1, the laboratory director failed to sign the PT attestation statement.
D6021	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 quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on lack of quality assessment records, the Quality Assessment procedure and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 9:35 am on 11/11/2021, the laboratory director failed to ensure the laboratory maintained a quality assessment program for 23 out of 23 months from 1/1/2020 - 11/11/2021. The findings include: 1. The Quality Assessment procedure stated that, "Laboratory Chart Auditing is performed to validate adherence to policies and procedures with feed back provided as applicable. The following will be audited on a random basis, minimally one chart monthly by the Laboratory Compliance Coordinator with results provided to clinic leadership." 2. At the time of the survey, the laboratory did not have documented chart audits from 1/1/2020 - 11/11 /2021.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of personnel records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report, CMS-209) at approximately 8: 30 am on 11/11/2021, the laboratory director failed to ensure prior to testing patients' specimens all personnel received documented training for two out of two testing

	personnel (identifiers #5 and #6) in 2020. The findings include: 1. On 9/29/2020, the laboratory employed testing personnel identifier #5 to perform complete blood cell count testing. 2. On 12/28/2020, the laboratory employed testing personnel identifier #6 to perform complete blood cell count testing. 3. At the time of the survey, the laboratory did not have training records for testing personnel identifiers #5 & #6.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on review of personnel records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report, CMS-209) at approximately 8: 30 am on 11/11/2021, the laboratory director failed to ensure that the laboratory established and maintained annual and six month competency assessments for six out of six testing personnel (identifiers #1 - #6) from 11/11/2019 - 11/11/2021. The findings include: 1. Testing personnel identifiers #1 - #4 did not have documented annual competency assessments performed in 2019 or 2020. 2. Testing personnel identifiers #5 and #6 did not have six month competency assessments performed in 2021. 3. At the time of the survey, the laboratory did not have documented annual or six month competency assessments for any of the listed testing personnel.