Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D0655988	04/25/2022
Name of Provider or Supplier	**Street Address, City, State**	
Uh Geneva Medical Center	870 West Main Street, Geneva, OH	

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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on record review and an interview with the Laboratory Manager (LM), Technical Supervisor (TS) #3 and TS#4, the laboratory failed to retain at least the previous two years of analytic system activity records for the Beckman Chemistry analyzer test system. All patient chemistry testing performed prior to 12/2021 were affected by this deficient practice. Findings Include: 1. Review of the laboratory's "LABORATORY SERVICES General Policies and Procedures Manual", approved via signature and date by the Laboratory Director on 12/14/2021 and provided for the inspection did not find any mention of retention requirements for any laboratory documentation. 2. The Inspector requested the laboratory's 2020, 2021 and 2022 patient requisitions for laboratory testing, interim test records, including instrument printouts, and the laboratory's corresponding final test reports from the LM. The LM provided a Remisol (middleware system) report and the final test report, however was unable to provide the Beckman chemistry analyzer printed results in 2020 and early in 2021 due to high volume throughput and the test system not retaining the previous two years of results. 3. The LM confirmed on 04/26/2022 at 10:45 AM that the laboratory's Beckman chemistry analyzer did not retain patient test results for at least the previous two years and was unable to provide the requested documentation on the date of nor within seven days after the inspection.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235

	As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on record review and interviews with the Laboratory Manager (LM), Technical Supervisor (TS) #3 and TS#4, the laboratory failed to establish and follow written policies and procedures to assess the competency of the Clinical Consultants (CC), Technical Consultants (TC), Technical Supervisors (TS) and General Supervisors (GS) based on the responsibilities of the positions and at a frequency determined by the laboratory, as specified in the personnel requirements in subpart M. All patient testing performed in five out of five specialties (Microbiology, Diagnostic Immunology, Chemistry, Hematology and Immunohematology) in this laboratory had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's "Competency Assessment" policy and procedure, provided for the inspection, found the following statements: "A personnel competency program is instituted to ensure that personnel are knowledgeable and skilled in their assigned duties. It includes periodic evaluation and documentation of competence of personnel to perform assigned duties... This procedure applies to competency assessment of phlebotomists, qualified testing personnel, and supervisory personnel." 2. Review of the laboratory's Form CMS-209, approved, signed and dated by the Laboratory Director on 04/20/2022, revealed, other than the Laboratory Director, four individuals listed as TC, three individuals listed as TS and four individuals listed as GS and all qualified by the Laboratory Director to function in the assigned positions. 3. Review of the laboratory's 2020, 2021 and 2022 competency assessment documentation, provided for the validation inspection, did not find any competency assessment documentation for the CC#2, TC#2, TC#3, TC#4, TC#5, TS#2, TS#3, TS#4, GS#2, GS#3, GS#4 and GS#5, based on the responsibilities of their assigned positions. 4. The Inspector requested the laboratory's competency assessment documentation for CC#2, TC#2, TC#3, TC#4, TC#5, TS#2, TS#3, TS#4, GS#2, GS#3, GS#4 and GS#5 based on the responsibilities of the positions from the LM. The LM confirmed the laboratory did not establish a policy and procedure for the assessment of the CC, TC, TS and GS, did not assess the competency of CC#2, TC#2, TC#3, TC#4, TC#5, TS#2, TS#3, TS#4, GS#2, GS#3, GS#4 and GS#5 based on the responsibilities of the assigned positions, at a frequency determined by the laboratory and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 04/25/2022 at 10:40 AM.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on record review and an interview with the Laboratory Manager (LM), the Technical Consultant (TC) failed to evaluate and document the competency of testing personnel (TP) #9 who was responsible for moderate complexity testing procedures at least semiannually during the first year the individual tested patient specimens. All patients tested by TP#9 in 2021 and 2022 had the potential to be affected by this

	deficient practice. Findings Include: 1. Review of the laboratory's Form CMS-209, provided on the date of the inspection, approved, signed and dated by the Laboratory Director on 04/20/2022, revealed one out of one newly listed individual and credentialed as a TP by the Laboratory Director who had performed patient moderately complex testing procedures as indicated by TP#9's initial demonstration of competence on 02/2021. 2. Review of the laboratory's "Competency Assessment" policy and procedure, provided on the date of the inspection, approved, signed and dated by the Laboratory Director, revealed the following competency assessment instructions: "b. The six-month evaluation of competency for the new employee will be documented on the Training Checklist which was also used for initial training. c. Annual employee competency will be documented using CAP Competency Assessment program. If retraining in any category or competency reassessment is necessary, it will be noted using the Competency Reassessment form." 3. The Inspector requested the semiannual competency assessment documentation for TP#9, during their first year of testing patient specimens, from the LM. The LM was unable to provide the semiannual competency assessment documentation for TP#9 on the date of the inspection. The interview occurred on 04/25/2022 at 10:25 AM.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on record review and an interview with the Laboratory Manager (LM), the Technical Consultant (TC) failed to evaluate and document five out of 14 annual competency assessments in 2021 for TP#19, TP#20, TP#21, TP#22 and TP#23 for the moderately complex Werfen blood gas testing procedures performed. All patients tested by TP#19, TP#20, TP#21, TP#22 and TP#23 in this laboratory in 2021 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's Form CMS-209 "Laboratory Personnel Report (CLIA)" revealed 14 individuals listed and credentialed by the Laboratory Director on 04/20/2022 to perform moderately complex Werfen blood gas testing procedures. 2. Review of the laboratory's "Competency Assessment" policy and procedure, provided on the date of the inspection, approved, signed and dated by the Laboratory Director, revealed the following competency assessment instructions: "c. Annual employee competency will be documented using CAP Competency Assessment program. If retraining in any category or competency reassessment is necessary, it will be noted using the Competency Reassessment form." 3. Review of the laboratory's 2021 and 2022 competency assessment documentation, provided on the date of the inspection, revealed five out of 14 TP with no indication that their competency had been assessed by the TC in 2021. 2021 2022 TP#19 none February TP#20 none March TP#21 none March TP#22 none none yet TP#23 none none yet 4. The Inspector requested the laboratory's 2021 competency assessment documentation indicating the TC's signature as the assessor of competency for TP#19, TP#20, TP#21, TP#22 and TP#23 from the LM. The LM was unable to provide the 2021 competency assessments for the TP listed above on the date of the inspection. The interview occurred on 04/25/2022 at 10: 55 AM.