Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D0342003	12/07/2022
Name of Provider or Supplier	**Street Address, City, State**	
Biomedical Laboratory	4504 Logan Way, Hubbard, 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
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 record review and an interview with the Laboratory Owner (LO), the Laboratory Director (LD) failed to attest to the routine integration of proficiency testing (PT) samples into the patient workload using the laboratory's routine methods for 19 out of 19 of the reviewed College of American Pathologists (CAP) PT events in 2021 and 2022. All patient testing performed in this laboratory in the specialties of Microbiology, Diagnostic Immunology, Chemistry and Hematology had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's "CAP Survey Processing, Handling and Reporting Checklist Policy", unapproved by the LD and provided for the inspection, found the following statement: "The attestation form must be signed by the director or designee and all technologists involved in the testing process." 2. Review of the laboratory's 2021 and 2022 CAP PT documentation did not find the LD's signature attesting to the routine integration of proficiency testing (PT) samples into the patient workload using the laboratory's routine methods. The signature of Testing Personnel (TP) #1, TP#3 and another individual not listed on the CMS-209 was found instead of the LD's signature. 3. The Inspector requested the LD's letter delegating PT attestation by the LD to a qualified and listed individual on the CMS-209 from the LO. The LO confirmed that the LD did not delegate this duty in writing and was unable to provide the requested documentation on the date of or within 7 days of the inspection. The interview occurred on 12/07/2022 at 10:09 AM.
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 an interview with the Laboratory Owner (LO), the laboratory failed to establish and follow written policies and procedures to assess and document the competency of General Supervisor (GS) #1, GS#2, GS#3 and GS#4, based on the responsibilities of the position and at a frequency determined by the laboratory, as specified in the personnel requirements in subpart M. All 424,968 patient testing in the specialties of Microbiology, Diagnostic Immunology, Chemistry and Hematology performed in 2021 and 2022 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's policy and procedure titled "Biomedical Laboratory Competency Assessment", provided for inspection review, did not find a policy and procedure for assessing the competency of the GS's based on the responsibilities of the position and at a frequency determined by the laboratory. 2. Review of the laboratory's Form CMS-209, approved via signature and date by the Laboratory Director (LD) on 12/07/2022, revealed the LD is also the sole Clinical Consultant (CC) and TS and four individuals are indicated as TPs and GSs. 3. Review of the laboratory's 2021 and 2022 competency assessment documentation, provided for the inspection, did not find competency assessment records for GS#1, GS#2, GS#3 or GS#4 based on the responsibility of the position. 4. The Inspector requested the laboratory's policy and procedure for the competency assessment of the GSs as well as the assessment documentation for GS#1, GS#2, GS#3 and GS#4 in 2021 and 2022 based on the responsibilities of the GS position from the LO. The LO confirmed the laboratory did not establish a policy and procedure for the assessment of the GSs, did not assess the competency of GS#1, GS#2, GS#3 and GS#4 based on the responsibilities of the position, at a frequency determined by the laboratory and was unable to provide the requested documentation on the date of or within 7 days of the inspection. The interview occurred on 12/07 /2022 at 11:30 AM.
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 record review and interviews with the Laboratory Owner (LO) and the Laboratory Director (LD), the LD failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing procedures performed in the specialties of Microbiology, Diagnostic Immunology, Chemistry and Hematology. All 424,968 patient testing procedures performed in 2021 and 2022 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's requested policies and procedures provided for the inspection, revealed the following new and revised policies and procedures that were unapproved via signature and date by the LD prior to implementation: "Calibrator and Control Positions and Stability on the ADVIA 1800" (in use on 04/16/2021) "CAP Survey

	Processing, Handling and Reporting Checklist Policy" (in use 07/01/2021, revised on 10/31/2022) "Biomedical Laboratory Competency Assessment" (in use 10/11/2022) 2. The Inspector requested the laboratory's approved policies and procedures by the LD from the LO. The LO and the LD stated they were under the impression that policy and procedure approval could be delegated to another individual and recently led to believe that only major revisions required the approval via the LD. LO confirmed the LD did not approve all of the laboratory policies and procedures via signature and date prior to implementation and was unable to provide the requested documentation on the date of the inspection. The interviews occurred on 12/07/2022 at 9:45 AM.
D6151	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463(b)(3)(4) (3) The director or technical supervisor may delegate to the general supervisor the responsiblity for providing orientation to all testing personnel; and (4) Annually evaluating and documenting the performance of all testing personnel. This STANDARD is not met as evidenced by: Based on record review and interviews with the Laboratory Owner (LO), the Laboratory Director (LD), Technical Supervisor (TS) and General Supervisor (GS) failed to evaluate and document competency assessment of Testing Personnel (TP) #1 and TP#3 in 2022. All 212,484 patient testing procedures in the specialties of Microbiology, Diagnostic Immunology, Chemistry and Hematology performed in 2022 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's policy and procedure titled "Biomedical Laboratory Competency Assessment" did not find any indication stating a qualified TS or GS are responsible for the assessment of TP's competency. 2. Review of the laboratory's Form CMS-209, approved via signature and date by the LD on 12/07/2022, revealed the LD is also the sole Clinical Consultant (CC) and TS and four individuals are listed as TPs and GSs. 3. Further review of the Laboratory's Form CMS-209 did not indicate TP#4 and TP#5 as a TS or GS as assigned and approved by the LD. 4. Review of the laboratory's 2022 competency assessment documentation, provided for the inspection, revealed the competency of TP#1 was assessed by TP#5 who was not assigned by the LD to function as a TS or GS. The competency of TP#3 was assessed by an individual not listed and assigned by the LD on the CMS-209 to function as a TS or GS. 5. The Inspector requested the 2022 competency assessment documentation for TP#1 and TP#3 completed by a qualified individual listed on the CMS-209 as a TS or GS. The LO confirmed that TP#1 and TP#3 had their 2022 competency assessed by two different individuals who were not listed and/or assigned as a TS or GS by the LD. The LO was unable to provide the requested documentation on the day of or within 7 days of the inspection. The interviews occurred on 12/07/2022 at 11:30 AM and via electronic mail (email) on 12/22/2022 at 4:23 PM.