

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D0328217	(X3) Date Survey Completed 06/08/2022
Name of Provider or Supplier Ohiohealth Berger Hospital Lab	Street Address, City, State 600 North Pickaway Street, Circleville, 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
D5485	<p>CONTROL PROCEDURES CFR(s): 493.1256(h)</p> <p>If control materials are not available, the laboratory must have an alternative mechanism to detect immediate errors and monitor test system performance over time. The performance of alternative control procedures must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on record review and an interview with the General Supervisor (GS) #1, the laboratory failed to perform and document alternative quality control for the wet preparation testing procedures performed when commercial control materials were not available. This deficient practice had the potential to affect 35 patients tested in the subspecialty of parasitology from 05/26/2021 through 05/26/2022. Findings Include: 1. Review of the laboratory's "Wet Prep BH-COR-MI-10", procedure found the following statement: "1. Trichomonas: Identification of Trichomonas is made by observation of characteristic forms. The organisms are approximately the same size and shape as WBCs, and in a wet prep can only be distinguished by their motility." 2. The Inspector requested the laboratory's wet preparation testing quality control documentation from the GS#1. The GS#1 confirmed the laboratory did not document wet preparation testing quality control procedures as stated in the procedure and was unable to provide the requested documentation on the date of the inspection. The interview occurred 06/08/2022 at 12:30 PM.</p>
D6102	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12)</p> <p>The laboratory director must 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</p>

results.

This STANDARD is not met as evidenced by:

Based on record review and interviews with the Laboratory Director (LD), and the General Supervisor (GS) #1, the Laboratory Director failed to ensure prior to testing patients' specimens, GS#1 had received the appropriate training, and had demonstrated they could perform all testing operations reliably to provide and report accurate results for the high complexity test procedures performed. This deficient practice had the potential to affect 597,491 patients tested under the specialties of chemistry, hematology, and microbiology from 02/14/2022 through 06/08/2022. 1. Review of the laboratory's policy and procedure titled "Competency Assessment OHL-QUA-PR-02, provided via electronic mail (email) on 05/26/2022 at 6:52 PM found the following statements: " 1. Documented competency assessment is required for individuals fulfilling the following personnel responsibilities outlined in Subpart M of the CLIA regulations: clinical consultant (CC), technical consultant (TC), technical supervisor' (TS), general supervisor (GS) and testing personnel (TP)." 2. The Inspector requested the competency assessment records for GS#1 from the LD and GS#1. 3. A form titled "Performance Assessment of Technical Supervisor and Consultant" dated 02/14/2022 with the name of GS#1 was provided. The form revealed a checklist of responsibilities only with no mention of competencies assessed. 3. The LD and GS#1 confirmed the laboratory did not perform a competency assessment for GS#1, and was unable to provide the requested documentation on the date of the inspection. The interviews occurred 06/08/2022 at 10:15 AM.