

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  44D2200945	<b>(X3) Date Survey Completed</b>  06/13/2024
<b>Name of Provider or Supplier</b>  Obion County Medical Clinic	<b>Street Address, City, State</b>  321 E Harper St, Troy, TN	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D3031</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(3)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the laboratory's quality control (QC) records, lack of records, and staff interview, the laboratory failed to retain six of twelve QC package inserts for the Abbott Cell Dyn Emerald used for complete blood count (CBC) patient testing in 2023 and 2024. The findings include: 1. Observation of the laboratory on 06/13/2024 at 11:00 am revealed the Abbott Cell Dyn Emerald instrument (Serial #030221) used for CBC patient testing. 2. A review of the laboratory's daily CBC QC records revealed the following: Lots N3289, L3289, H3289 used on 11/17/2023 Lots N4008, L4008, H4008 used on 03/27/2024 3. The laboratory was unable to provide the QC package inserts for lots N3289, L3289, H3289, N4008, L4008, H4008. 4. An interview on 06/13/2024 at 1:00 pm with the technical consultant and office manager confirmed the survey findings.</p>
<b>D6033</b>	<p><b>TECHNICAL CONSULTANT-MODERATE COMPEXITY</b> CFR(s): 493.1409</p> <p>The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on a review of the Department of Health and Human Services Centers for</p>

Medicare and Medicaid Services Laboratory Personnel Report (CLIA) (Form CMS-209), laboratory personnel records, and staff interviews, the initial competencies for two of two new testing personnel (TP) were performed by a person that did not meet the minimum educational and experience regulatory requirements for performing technical consultant duties (Refer to D6034).

**D6034**

**TECHNICAL CONSULTANT QUALIFICATIONS**  
CFR(s): 493.1411

The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs moderate complexity tests or procedures. The director of a laboratory performing moderate complexity testing may function as the technical consultant provided he or she meets the qualifications specified in this section.

This STANDARD is not met as evidenced by:  
Based on a review of the Department of Health and Human Services Centers for Medicare and Medicaid Services Laboratory Personnel Report (CLIA) (Form CMS-209), laboratory personnel records, and staff interviews, the initial competencies for two testing personnel (two of two new personnel reviewed) were performed by a person that was not qualified for the technical consultant position in 2023. The findings include: 1. A review of the Form CMS-209 revealed three testing personnel and one technical consultant listed on the form. 2. A review of the laboratory personnel records revealed the following: Initial competencies for TPs two and three were signed by a person not listed on the Form CMS-209. Documentation to qualify the person who signed the initial competencies for TPs two and three was not available on the survey date (06/13/2024). 3. The survey findings were confirmed in an interview with the technical consultant and office manager on 06/13/2024 at 1:00 p. m. and an electronic interview with the office manager on 06/20/2024 at 10:30 a.m.

**D6046**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:  
Based on a review of the Department of Health and Human Services Centers for Medicare and Medicaid Services Laboratory Personnel Report CLIA (Form CMS-209), laboratory personnel records, and staff interviews, the technical consultant (TC) failed to perform competency assessments for testing personnel (TP) (two of three reviewed) who performed complete blood count (CBC) patient testing in 2023. The findings include: 1. A review of Form CMS-209 revealed three TP and one TC for moderately complex CBC patient testing . 2. A review of the laboratory personnel records revealed the following: TP two initial competency performed on 09/08/2023 was not performed by the TC of record on the Form CMS-209. TP three initial competency performed on 10/09/2023 was not performed by the TC of record on the

Form CMS-209. The TC did not perform TP three competency titled "six months" performed on 12/06/2023. 3. An interview on 06/13/2024 at 1:00 pm with the TC and office manager confirmed the survey findings.