

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 36D0877438	<b>(X3) Date Survey Completed</b> 03/10/2021
<b>Name of Provider or Supplier</b> Gastroenterology Clinic & Endoscopy	<b>Street Address, City, State</b> 1622 E Market Street, Warren, OH	
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>D5417</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on record review and an email interview with Testing Personnel (TP) #3, the laboratory failed to ensure that the Histopathology Giemsa stain and Schiff's reagent was not used when it had exceeded its expiration date. All patient tissue biopsy testing conducted in the specialty of Histopathology between 02/01/2018 through 04/12/2018 and 02/01/2021 through current date for all Giemsa staining and between 06/29/2018 through 07/28/2018 for Periodic Acid Schiff (PAS) and Alcian Blue (AB)/PAS staining had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's "Special Stains/Reagents Lot Number and Expiration Log", provided for the virtual inspection, revealed the following Giemsa stain records: Lot Number Expiration Date Opened Date 401504 01/2018 442650 04/13/2018 and 515590 01/2021 No new lot number indicated as opened 2. Further review of the laboratory's "Special Stains/Reagents Lot Number and Expiration Log", provided for the virtual inspection, revealed the following Schiff's stain records: Lot Number Expiration Date Opened Date 377613 06/28/2018 410350 07/29/2018 3. The inspector requested the laboratory's Giemsa and Schiff's staining documentation showing the Giemsa and Schiff's stains were not used beyond their expiration dates for patient tissue biopsy testing procedures from TP#3. TP#3 confirmed in an email on 02/25/2021 at 6:46 AM that "...I do see that the reagent was saying it expired at that date...it had to be a human error" and was unable to provide any other documentation.</p>
<b>D6151</b>	GENERAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1463(b)(3)(4)

(3) The director or technical supervisor may delegate to the general supervisor the responsibility 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 of the laboratory's policies and procedures and competency assessment documentation, the Laboratory Director, Technical Supervisor (TS) or General Supervisor (GS) failed to evaluate and document the assessment of competency of Testing Personnel (TP) #4. All patient tissue biopsy grossing procedures performed in the specialty of Histopathology by TP#4 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's policy and procedure titled "Competency Assessment Policy", found the following statements: "Who is Responsible to Assess? Under the regulations, not just anyone can perform the assessments. The individual conducting competency assessment must be qualified. Depending on whether the lab performs high or moderate complexity testing, only those individuals who meet the regulatory qualifications, and who have the required level of education and experience, such as a technical/general supervisor, or clinical/technical consultant can be delegated, in writing." 2. Review of the laboratory's Form CMS-209, approved via signature and date by the Laboratory Director on 02/09/2021, revealed the following laboratory positions assigned by the Laboratory Director: Clinical Consultants (CC) - three individuals (Laboratory Director and two CC) TS - one individual (Laboratory Director) GS - two individuals (Laboratory Director and one CC) TP -six individuals 3. Further review of the Laboratory's Form CMS-209 did not indicate TP#3 as a CC, TS or GS as assigned and approved by the Laboratory Director. 4. Review of the laboratory's 2019 and 2020 competency assessment documentation, provided for the virtual inspection, did not find records showing that a TS or GS conducted the competency assessment for TP#4 in 2020 who performed high complexity patient tissue biopsy grossing procedures, however found TP#3 assessed the competency of TP#4 on 02/04/2020.