Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D1002988	(X3) Date Survey Completed 01/21/2025
Name of Provider or Supplier Ibrahim Zayneh Md Llc	**Street Address, City, State** 2127 25th Street, Portsmouth, 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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: ITEM 1 Based on record review and an interview with the Histology Technician (HT), the laboratory failed to follow their "Proficiency Testing" policy and procedure. This deficient practice had the potential to affect seven out of seven patients tested in the specialty of Histopathology from 01/16/2024 through 12/04/2024. Findings Include: 1. Review of the policy and procedure titled "Proficiency Testing" approved via signature and date by the Laboratory Director on 01/29/2024 and again on 01/07 /2025 found the following statements: "Semi-Annually, the Tech will send three cases of Mohs containing the Original Slides, label it with only the surgical case number, and send it out for microscopic examination by another Provider" 2. Review of patient logs titled "CLIA #36D1002988" from 07/11/2023 through 01/14/2025 found the following Mohs patients tested: Case # Date 24M1183 1/16/24 24M1184 1/16/24 24M1185 1/30/24 24M1186 12/3/24 24M1187 12/3/24 24M1188 12/4/24 24M1189 12 /4/24 3. The inspector requested the 2024 peer review documents from the HT. The HT confirmed the laboratory did not send any Mohs cases out for microscopic examination by another provider and was unable to provide the requested information. The interview occurred on 01/21/2025 at 10:30 AM. ITEM 2 Based on record review and an interview with the Histology Technician (HT), the laboratory failed to follow their "Quality Assurance for Routine Stains" policy and procedure. This deficient practice had the potential to affect one out of seven patients tested in the subspecialty of Histopathology from 01/16/2024 through 12/04/2024. 1. Review of the policy and procedure titled "Quality Assurance for Routine Stains" approved via signature and

	date by the Laboratory Director on 01/29/2024 and again on 01/07/2025 found the following statements: "1. A quality control slide will be run each day the lab operates" 2. Review of quality control logs titled "Quality Assurance Quality Control Slides" from 11/21/2023 through 01/14/2025 found the following dates for quality control slide preparations: 01/16/2024 12/03/2024 12/04/2024 12/17/2024 3. Review of patient logs titled "CLIA #36D1002988" from 07/11/2023 through 01/14/2025 found the following Mohs patients tested: Case # Date 24M1183 1/16/24 24M1184 1/16/24 24M1185 1/30/24 24M1186 12/3/24 24M1187 12/3/24 24M1188 12/4/24 24M1189 12/4/24 3. The inspector requested the 01/30/2024 quality control slide documentation from the HT. The HT confirmed the laboratory did not document quality control for 01/30/2024 and was unable to provide the requested information. The interview occurred on 01/21/2025 at 10:45 AM.