

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D1093502	(X3) Date Survey Completed 08/06/2024
Name of Provider or Supplier Family Health Services Of Erie County	Street Address, City, State 1912 Hayes Avenue, Sandusky, 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
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation and an interview with the Charge Nurse, it was determined that the laboratory failed to follow manufacturer's instructions for accurate specimen labeling to ensure the integrity of patient urine specimens for waived urinalysis testing. The laboratory failed to ensure that two out of two patient specimens observed on 08/06/2024, the day of the inspection, were labeled with accurate and unique patient identifiers. Findings include: 1. The surveyor toured the laboratory on the day of the inspection, 08/06/2024 at 1:14 PM. 2. The surveyor noted two urine specimens on the laboratory counter. Each specimen container was placed on a paper towel a few inches part.. The urine specimens were labeled as follows: Specimen Container Paper Towel 1 [unlabeled] "[patient first name] #1" 2 [unlabeled] "[patient last name] #2" 3. The surveyor reviewed the manufacturer's instructions regarding specimen labeling: "...If a Barcode reader is installed, holding the Barcode reader over the barcode on the specimen container... If a Barcode reader is not installed, enter the ID manually using the keypad..." 4. An interview with the Charge Nurse confirmed that the laboratory failed to label two out of two urine specimens with patient identification to ensure the integrity of specimens during waived urinalysis testing. The interview occurred on 08/06/2024 at 1:18 PM.</p>
D5980	<p>PPM LABORATORY DIRECTOR CFR(s): 493.1355</p> <p>The laboratory must have a director who meets the qualification requirements of 493.</p>

1357 and provides overall management and direction in accordance with 493.1359.

This CONDITION is not met as evidenced by:

Based on record review and interviews with the Medical Director and the Charge Nurse, the laboratory failed to ensure that the position of Laboratory Director was filled according to the qualification requirements of 493.1357 of this subpart in order to provide overall management and direction in accordance with 493.1359 of this subpart. This deficient practice had the potential to affect 12,903 patients tested at this laboratory from 11/30/2023 to 08/06/2024. Findings include: 1. Review of the CMS-116 form found an individual listed as the Laboratory Director. 2. Review of the laboratory's policies and documentation found a current CLIA PPM certificate with same individual listed at the Laboratory Director. 3. An interview with the Medical Director and the Charge Nurse confirmed that the Laboratory Director listed on the CMS-116 form left the practice on 11/30/2023, that the laboratory failed to ensure the position was filled and that CMS received official notification of that change. The interviews occurred on 08/06/2024 at 12:43 PM.