

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  23D0701946	<b>(X3) Date Survey Completed</b>  11/05/2018
<b>Name of Provider or Supplier</b>  O L Matthews Md	<b>Street Address, City, State</b>  3011 W Grand Blvd Suite 466, Detroit, MI	
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>D5201</b>	<p>CONFIDENTIALITY OF PATIENT INFORMATION CFR(s): 493.1231</p> <p>The laboratory must ensure confidentiality of patient information throughout all phases of the total testing process that are under the laboratory's control.</p> <p>This STANDARD is not met as evidenced by: . Based on observation and interview, the laboratory failed to ensure patient confidentiality was maintained for all phases of laboratory testing for four (August to November 2018) of four months audited. Findings include: 1. On November 5, 2018 at approximately 10:05 AM during a tour of the laboratory the surveyor observed there was no documentation of laboratory testing worksheets and patient testing printouts to review. 2. On November 5, 2018 at approximately 11:00 AM when queried, the office manager was not able to provide the surveyor documentation to all phases of laboratory testing. 3. On November 5, 2018 at approximately 11:30 AM, a phone conversation with testing personnel #1 as listed on the CMS-209 confirmed the documentation for all phases of laboratory testing was not available on-site and that all testing was stored at the testing personnel's home.</p>
<b>D5415</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by:</p>

. Based on observation and interview, the laboratory failed to label two (diluent and wash) of three bottles on the TOSOH chemistry/endocrinology instrument with the preparation and/or expiration date when first put into use. Findings include: 1. On November 5, 2018 at approximately 10:05 AM during a tour of the laboratory, the surveyor observed reagent bottles in use on the chemistry TOSOH instrument that did not have documentation of a preparation and/or expiration date as follows: a. diluent - preparation and/or expiration date b. wash - preparation and/or expiration date 2. On November 5, 2018 at approximately 11:45 AM, a phone conversation with testing personnel #1 as listed on the CMS-209 confirmed the reagent bottles were not labeled.

**D5417**

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT  
CFR(s): 493.1252(d)

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.

This STANDARD is not met as evidenced by:

. Based on observation and interview, the laboratory was using the TOSOH chemistry /endocrinology instrument diluent reagent for five (July to November 2018) of five months of testing that had exceeded the manufacturer's expiration date. Findings include: 1. On November 5, 2018 at approximately 10:05 AM during a tour of the laboratory, the surveyor observed TOSOH diluents in the refrigerator that exceeded the manufacturer's expiration date as follows: a. lot # H880045 (2 boxes) - expiration date of July 31, 2018 b. lot # HX80048 - expiration date of September 30, 2018 2. During the interview on November 5, 2018 at approximately 11:45 AM, the office manager confirmed that expired reagents were in use.