

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  14D1051792	<b>(X3) Date Survey Completed</b>  01/15/2019
<b>Name of Provider or Supplier</b>  O'Hare Clinical Labs	<b>Street Address, City, State</b>  4909 W Division St Ste #302, Chicago, IL	
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>D5403</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on observation, review, and interview; the laboratory's procedure manual did not include all required information applicable to the test procedure. Findings include: 1. There were no written procedures that explained how patients' specimens are sent out for referral. 2. There was a lack of documentation to show the reportable range for all test results for the test system as verified. The laboratory only documented the verified reportable range for analytes it deemed as elevated or panic values. Not every analyte it reports. 3. The were no written procedures that described the laboratory's system for entering results in the patient record and reporting patient results including,</p>

	<p>when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. 4. There were no procedures that described the course of action to take if a test system becomes inoperable. 5. On 01/15/19 at 11:00 AM, the laboratory director confirmed the surveyor's findings.</p>
<p><b>D5407</b></p>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures manual and interview; procedures and /or changes in procedures were not approved, signed, and dated by the current laboratory director before use. Findings include: 1. Review of the laboratory's procedures manual revealed that the laboratory procedures were not approved, signed, and dated by the current laboratory director. 2. On 01/15/18 at 10:30 AM, the laboratory director confirmed the surveyor's findings.</p>
<p><b>D5413</b></p>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on observation and interview; the laboratory failed to define, monitor, and document the condition for which it incubated complete blood count (CBC) specimens. Findings include: 1. On 01/15/19 at 9:00 AM, the surveyor performed a walk-through of the laboratory where she observed that there was a Thermolyne Type 16500 Dri-Bath incubator on the counter next to the CBC analyzer. The surveyor observed that there was no thermometer to monitor the temperature of the Dri- Bath. 2. On 01/15/19 at 9:14 AM, the surveyor asked testing personnel what the incubator was used for. Testing personnel told the surveyor that whenever there was a high MCHC, patient's specimens are incubated at 37 C and rerun. 3. The surveyor asked testing personnel how the laboratory determined that the Dri-Bath was at the proper temperature. Testing personnel pointed to the knob used to set the temperature. 4. There was no documentation to show that the temperature of the Dri-Bath was recorded. 5. On 01/15/19 at 10:00 AM, the laboratory director confirmed the surveyor's findings.</p>
<p><b>D5415</b></p>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> 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</p>

when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

Based on observation and interview; control materials were not labeled to indicate the following: \*Identity \*Storage requirements \*Preparation and expiration dates

Findings include: 1. Observation of 1 of 2 refrigerators revealed that the laboratory stored aliquot quality control (QC) material for TSH, FT4, and PSA in the freezer of the refrigerator. 2. There was no record to show that the laboratory documented the following information for aliquot QC material TSH, FT4, and PSA: a. Identification such as lot number b. Storage requirements such as temperature c. Preparation and expiration dates 3. On 01/15/19 at 10:30 AM, the laboratory director confirmed the surveyor's findings.

**D5463**

**CONTROL PROCEDURES**

CFR(s): 493.1256(d)(7)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Over time, rotate control material testing among all operators who perform the test. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of laboratory records and interview; the laboratory did not rotate control (QC) material testing among all operators who perform the test. Findings include: 1. Review of Laboratory Personnel Report - CLIA (FORM CMS 209) revealed that the laboratory has a total of 2 testing personnel who perform the following tests: a. Complete Blood Count (CBC) b. PT- INR c. Endocrinology d. Routine Chemistry e. Microscopic Urinalysis 2. Review of laboratory records revealed that 1 of 2 testing personnel performed all QC and maintenance procedures from September 1, 2018 to January 15, 2019 for the following laboratory tests: a. Complete Blood Count (CBC) b. PT- INR c. Endocrinology d. Routine Chemistry e. Microscopic Urinalysis 3. On 01/15/19 at 1:30 PM, the laboratory director confirmed the surveyor's findings.

**D6049**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(8)(iii)

The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.

This STANDARD is not met as evidenced by:

Based on review of laboratory records and interview; the procedures for evaluation of the competency of the staff failed to include the following: \*quality control records \*preventive maintenance records Findings include: 1. Review of Laboratory Personnel Report - CLIA (FORM CMS 209) revealed that the laboratory has a total of 2 testing personnel who perform the following tests: a. Complete Blood Count (CBC) b. PT- INR c. Endocrinology d. Routine Chemistry e. Microscopic Urinalysis 2.

Review of laboratory records revealed that 1 of 2 testing personnel performed all QC and maintenance procedures from September 1, 2018 to January 15, 2019 for the following laboratory tests: a. Complete Blood Count (CBC) b. PT- INR c. Endocrinology d. Routine Chemistry e. Microscopic Urinalysis 3. On 01/15/19 at 1:30 PM, the laboratory director confirmed the surveyor's findings.