

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  52D0989506	<b>(X3) Date Survey Completed</b>  05/30/2018
<b>Name of Provider or Supplier</b>  Oakleaf Clinics Sc	<b>Street Address, City, State</b>  3802 W Oakwood Mall Dr, Eau Claire, WI	
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>D5447</b>	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g)</p> <p>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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of laboratory quality control records, manufacturer's package insert instructions, and interview with the laboratory supervisor the laboratory does not use an elevated serum bilirubin control for monitoring the abnormal range of neonatal bilirubin testing. The laboratory also does not use an elevated serum glucose control to check the clinically relevant range for high glucose results. Item #1 Findings include: 1. Review of laboratory quality control (QC) records for the bilirubin assay show that two levels of QC are performed on a daily basis. The current in use lot of Bio-Rad Liquid Assayed Multiquel QC had the following QC ranges: Level 1: 0.469-0.840 mg/dL Level 2: 2.81-3.38 mg/dL 2. Review of QC records for the bilirubin assay show that an elevated serum based bilirubin control for monitoring the abnormal range of neonatal bilirubin's is not assayed when performing neonatal bilirubin testing. 3. Interview with the laboratory supervisor on May 30, 2018 at 12:15 PM confirms that an elevated serum based bilirubin control is not used to monitor the abnormal range of neonatal bilirubin's. Item #2 Findings include: 1. Review of laboratory QC records for the glucose assay show that two levels of QC are performed on a daily basis. The current in use lot of Bio-Rad Liquid Assayed Multiquel QC had the following QC ranges: Level 1: 48.3-60.7 mg/dL Level 2: 101-119 mg/dL 2. Review of the manufacturer's package insert</p>

instructions state QC should check the clinically relevant range. 3. Interview with the laboratory supervisor on May 30, 2018 at 12:15 PM confirms that glucose quality control does not cover the clinically relevant range for elevated glucose testing.

**D6004**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(a)(b)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

Based on laboratory record review and interview with the laboratory supervisor, the laboratory director has designated in writing responsibilities to an individual who is not a qualified technical consultant to perform those duties. Findings include: 1. The laboratory director may delegate to a technical consultant, in writing, the responsibilities in : 493.1407(e)(3), (4), (5), (6), (7), (11), (12), and (13). 2. The laboratory director has written delegation to an individual that is not a qualified technical consultant to perform those responsibilities. 3. Interview with the laboratory supervisor on May 30, 2018 at 11:30 AM confirms that the laboratory director has not delegated responsibilities in writing to a qualified technical consultant to perform the responsibilities in 493.1407(e)(3), (4), (5), (6), (7), (11), (12), and (13).