Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0997907	(X3) Date Survey Completed 10/15/2019
Name of Provider or Supplier Oakleaf Clinics Pine Grove Family Medicine	**Street Address, City, State** 2741 N Clairemont Ave Ste D, Eau Claire, WI	
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
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on surveyor review of urine microscopic test reports, laboratory procedures, and interview with the laboratory director, the acceptable test results in the procedure do not match the results reported from the laboratory information system (LIS). Findings include: 1. Review of the "Microscopic Urinalysis" procedure states results for bacteria and mucous in an urine microscopic test are reported as "Trace, 1+, 2+, 3+, or 4+." 2. Review of the LabDaq LIS shows the urine bacteria and mucous results available for reporting are "Few", "Moderate", or "Many." 3. Interview with the laboratory director on October 15, 2019 at 3:10 PM confirms the results available to report from the LIS for urine bacteria or mucous are not the results that the approved procedure state should be reported.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

	This STANDARD is not met as evidenced by: Based on surveyor review of reference (normal) ranges in the hematology procedure with those on patient test reports, and interview with the laboratory director, reference (normal) ranges on patient reports are not consistent with the reference ranges in the approved procedure. Findings include: 1. Comparison of the reference (normal) ranges shown in the "ABX Micros 60-Hematology Procedure" with the reference ranges on patient reports from the LabDaq laboratory information system (LIS) show that reference ranges available on patient reports are not consistent with the reference ranges in the approved procedure. Reference Ranges from the LabDaQ (LIS) patient report versus the hematology procedure: (All reference ranges listed are for a male): White Blood Cell (WBC) count: Procedure: 4.0-11.0 per cubic millimeter LabDaq Report: 4.0-11.5 K/uL Red Blood Cell (RBC) count: Procedure: 4.15-5.55 per cubic millimeter LabDaq Report: 4.45-5.61 M/uL Hemoglobin: Procedure: 12.9-17.3 gm/dL LabDaq Report: 14.0-17.0 g/dL Hematocrit: Procedure: 38-51% LabDaq Report: 42.0-52.0 % Mean Cellular Volume (MCV): Procedure: 82-99 fL LabDaq Report: 79.0-101.0 fL Mean Corpuscular Hemoglobin (MCH): Procedure: 32-36 % LabDaq Report: 31.0-36.0 g/dL 2. Further review of the patient report shows that reference ranges are not available for the differential % values for granulocytes, lymphocytes, and monocytes. 3. Interview with the laboratory director on October 15, 2019 at 3:10 PM confirms the reference ranges on patient reports used for the evaluation of test results are not consistent with the reference ranges in the approved laboratory procedure.