

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2186592	(X3) Date Survey Completed 04/08/2021
Name of Provider or Supplier Oswald's Pharmacy & Medical Equipment	Street Address, City, State 88 W Gartner Rd - Ste 114, Naperville, IL	
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
D5441	<p>CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g)</p> <p>(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on record review, manual, lack of documentation, and an interview with the laboratory director (LD), the laboratory failed to establish control procedures that monitor the accuracy and precision of the complete analytic process for testing performed in the subspecialty of Virology for 1100 patients. Findings: 1. The laboratory's manual, March 2021 quality assurance (QA) report, Healgen manufacturer's Emergency Use Authorization (EUA) for Coronavirus 19 (COVID-19), and the Clinical Laboratory Improvement Amendments (CLIA) test volume worksheet were reviewed. 2. The laboratory used Healgen COVID-19 IgG/IgM Rapid Test Cassettes. 3. Review of the QA report and the manufacturer's EUA revealed the following: *Control standards were not supplied with the kits. *Each cassette has an internal procedural control to confirm sufficient specimen volume. *Manufacturer recommended the use of positive and negative controls to confirm test procedure and test performance of the cassettes. *QA report stated that the laboratory was unable to obtain controls for the COVID-19 Rapid Test. 4. Further review of the QA records showed the manufacturer did not provide direction or assistance to the laboratory for</p>

the purchasing of the controls needed for its COVID-19 Rapid kit. However, the laboratory failed to perform and document control procedures with external controls each day of patient testing. 5. The laboratory's manual failed to include a written quality control procedure or individual quality control plan (IQCP) for the Virology testing performed using the Healgen test system, prior to testing patients. 6. During the period of 07/2020 through 04/2021, the laboratory had tested 1100 patients. 7. On an Initial survey conducted on 04/08/2021 at 2:30 PM, the LD confirmed the above findings.