

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D0656465	(X3) Date Survey Completed 11/13/2024
Name of Provider or Supplier Holzer Hospital Foundation Db a Holzer	Street Address, City, State 2619 Sr 850 Building, Bidwell, OH	
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
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on record review and an interview with the Executive Director of Laboratory Services (EDLS), the laboratory failed to follow the Ventana manufacturer's instructions for the negative reagent control. This deficient practice had the potential to affect 153 out of 153 patients tested under the specialty of Histopathology from 09/24/2024 to 11/12/2024. Findings Include: 1. Review of the policy and procedure titled "Evaluation of Immunohistochemical Control Materials" approved and signed by the Laboratory Director on 01/16/2024 found the following statement: "If using a biotin-based detection system (e.g. Ventana iView detection kit), a negative reagent control must be prepared and stained along with the patient specimen. The negative reagent control is prepared from the actual patient specimen for which the antibody will be performed." 2. Review of the manufacturer's instructions titled "OptiView DAB IHC Kit" and "Ultraview Universal DAB Detection Kit" found the following statement: "A negative reagent control must be run for every specimen to aid in the interpretation of results" 3. The inspector requested 2024 negative reagent control records the for the OptiView DAB IHC Kit and the Ultraview Universal DAB Detection Kit from the EDLS. The EDLS confirmed the laboratory did not follow the manufacturer's instructions for the negative reagent control and was unable to provide the requested documents. The interview occurred on 11/13/2024 at 12:45 p.m.</p>
D5485	<p>CONTROL PROCEDURES CFR(s): 493.1256(h)</p>

If control materials are not available, the laboratory must have an alternative mechanism to detect immediate errors and monitor test system performance over time. The performance of alternative control procedures must be documented.

This STANDARD is not met as evidenced by:

Based on record review and an interview with the Executive Director of Laboratory Services (EDLS), the laboratory failed to perform and document alternative quality control for the wet mount testing procedures performed when commercial control materials were not available. This deficient practice had the potential to affect 17 out of 17 patients tested in the subspecialty of Mycology from 09/24/2024 through 11/12/2024. Findings Include: 1. Review of the laboratory's electronic policies and procedures found no mention of quality controls for wet mounts created and used to confirm the presence or absence of yeast from a culture media plate. 2. The Inspector requested the laboratory's wet mount testing quality control documentation from the EDLS. The EDLS confirmed the laboratory did not perform and document wet mount test quality control procedures and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 11/13/2024 at 1:30 p.m.