

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D0333185	(X3) Date Survey Completed 02/13/2018
Name of Provider or Supplier Harrison Community Hospital Laboratory	Street Address, City, State 951 E Market Street, Cadiz, 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
D5407	<p>PROCEDURE MANUAL 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 record review and an interview with the General Supervisor (GS), the laboratory failed to have procedures approved, via signature and date, by the current Laboratory Director before use. Findings Include: 1. Review of the laboratory's "Serology, Urinalysis and Bodily Fluids", "DXC 600" and "Hematology" policy and procedure manuals, provided on the date of the inspection, found the policies and procedures were approved, via signature and date, by a physician not listed on the CMS 209 form. 2. GS #1 confirmed the current Laboratory Director did not approve the laboratory's policies and procedures, via signature and date. The interview occurred on 2/13/2018 at 1:41 PM.</p>
D5807	<p>TEST REPORT CFR(s): 493.1291(d)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and an interview with the General Supervisor (GS), the laboratory failed to report all of the correct "reference intervals" units, as determined by the laboratory and approved by the Laboratory Director, to the authorized person ordering the tests and responsible for using the test results. Findings Include: 1.</p>

Review of the laboratory's "Normal Values-Laboratory" policy and procedure, provided on the date of the inspection, revealed the following analyte reference range approved by the Laboratory Director: Albumin 3.5-5.0 mg/dl 2. Review of one out of one of the laboratory's patient test reports, provided on the date of the inspection, revealed the following reported analyte reference range: Albumin 3.5-5.0 G/DL 3. GS #2 confirmed the laboratory did not report the correct Albumin "reference intervals" units, as determined by the laboratory and approved by the Laboratory Director, to the authorized person ordering the tests and responsible for using the test results. The interview occurred on 2/13/2018 at 2:32 PM.