

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D0233677	(X3) Date Survey Completed 01/24/2018
Name of Provider or Supplier Welch Community Hospital	Street Address, City, State 454 Mcdowell Street, Welch, WV	
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
D2087	<p>ROUTINE CHEMISTRY CFR(s): 493.841(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on review of the College of American Pathologists (CAP) proficiency testing (PT) records and interview with the Laboratory Manager (LM), the laboratory failed to achieve satisfactory performance for the analytes of Carbamazepine, Digoxin, Gentamicin, Phenobarbital, Phenytoin, and Valproic Acid for PT event C-C 2016 General Chemistry/Therapeutic Drugs. The findings include: 1. Review of the C-C 2016 CAP proficiency testing records identified the results for Carbamazepine, Digoxin, Gentamicin, Phenobarbital, Phenytoin, and Valproic Acid were 60%. 2. On 1/23/18 at approximately 11:00 AM, the LM confirmed the findings.</p>
D2173	<p>COMPATIBILITY TESTING CFR(s): 493.863(a)</p> <p>Failure to attain an overall testing event score of at least 100 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by: Based on review of the College of American Pathologists (CAP) proficiency testing (PT) records and interview with the Laboratory Manager (LM), the laboratory failed to achieve satisfactory performance for compatibility testing for J-A 2017 Transfusion Medicine(Comp). The findings include: 1. Review of the CAP proficiency testing records identified the result for J-A 2017 Transfusion Medicine(Comp) was 80%. 2. On 1/23/18 at approximately 11:00 AM, the LM confirmed the findings.</p>

CONTROL PROCEDURES

CFR(s): 493.1256(d)(3)(ii)(g)

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 qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policy and procedure manual, "QuickVue+ Strep A test" manufacturer's instructions, quality control records, "Strep A Internal and External Quality Control Log", "QuickVue+ Strep A test" patient records and interview with the Laboratory Manager (LM), the laboratory failed to perform and document a positive and negative control 308 of 346 days of patient testing in 2016 and 320 of 357 days of patient testing in 2017 for the "QuickVue+ Strep A test". Record review was from 1/1/16 to 12/31/17. The findings include: 1. Review of the laboratory's policy and procedure manual identified a policy "Quality Assessment-Waived Testing Kits", which states "As part of the laboratory's quality assurance plan, positive and negative external controls will be run with each shipment of a new lot number, with each shipment date or monthly on waived testing kits." 2. Review of the manufacturer's instructions for the "QuickVue+ Strep A test" identified the "QuickVue+ Strep A test" is "CLIA Complexity: Moderate". 3. On 1/23/18 at approximately 11:00 AM, the LM stated that she did not know the "QuickVue+ Strep A test" was "CLIA Complexity: Moderate". 4. Review of quality control records for the "QuickVue+ Strep A test" identified documentation of quality control for the following days in 2016: 1/1/16, 1/31/16, 2/1/16, 2/15/16, 2/25/16, 3/5/16, 3/13/16, 3/18/16, 3/23/16, 3/28/16, 3/29/16, 3/30/16, 3/31/16, 4/2/16, 4/9/16, 4/10/16, 4/15/16, 4/21/16, 4/23/16, 5/3/16, 5/8/16, 5/17/16, 5/24/16, 6/2/16, 6/16/16, 8/20/16, 9/3/16, 9/27/16, 10/1/16, 11/10/16, 11/12/16, 11/21/16, 11/22/16, 12/7/16, 12/15/16, 12/19/16, and 12/26/16. 5. Review of quality control records for the "QuickVue+ Strep A test" identified documentation of quality control for the following days in 2017: 1/3/17, 1/9/17, 1/14/17, 1/20/17, 1/25/17, 2/3/17, 2/4/17, 2/5/17, 2/7/17, 3/1/17, 3/16/17, 3/20/17, 3/25/17, 3/29/17, 4/13/17, 4/24/17, 5/11/17, 5/20/17, 5/23/17, 5/28/17, 6/5/17, 6/16/17, 7/3/17, 8/13/17, 9/13/17, 9/30/17, 10/21/17, 11/2/17, 11/11/17, 11/16/17, 11/22/17, 11/23/17, 11/28/17, 12/8/17, 12/12/17, and 12/18/17. 6. Review of the laboratory's "QuickVue+ Strep A test" patient records identified patient testing was performed on the following days in 2016: 1/1/16 to 6/7/16, 6/9/16 to 6/30/16, 7/3/16 to 7/8/16, 7/11/16 to 7/15/16, 7/18/16, 7/20/16, 7/22/16, 7/24/16, 7/25/16, 7/27/16 to 7/30/16, 8/1/16 to 8/10/16, 8/12/16, 8/14/16 to 8/19/16, 8/21/16 to 8/27/16, 8/29/16 to 8/31/16, 9/2/16 to 9/16/16, 9/18/16 to 9/30/16, and 10/1/16 to 12/31/16. 7. Review of the laboratory's "QuickVue+ Strep A test" patient records identified patient testing was performed on the following days in 2017: 1/1/17 to 1/5/17, 1/7/17 to 4/14/17, 4/16/17 to 6/23/17, 6/25/17 to 8/1/17, 8/3/17 to 8/18/17, 8/20/17 to 8/22/17, 8/24/17 to 9/1/17, 9/2/17, 9/4/17 to 9/30/17, and 10/1/17 to 12/31/17. 8. On 1/23/18 at approximately 11:00 AM, the LM confirmed the findings.