

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D0233677	(X3) Date Survey Completed 03/02/2022
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
D0000	An announced, on site, routine recertification survey was conducted at Welch Community Hospital on March 1 and March 2 2022, by the West Virginia Office of Laboratory Services. The laboratory was surveyed to assess compliance with the Federal Clinical Laboratory Improvement Amendment (CLIA) regulations under 42 CFR 493. Specific deficiencies are explained below.
D3025	<p>REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(d)</p> <p>Investigation of transfusion reactions. The facility must have procedures for preventing transfusion reactions and when necessary, promptly identify, investigate, and report blood and blood product transfusion reactions to the laboratory and, as appropriate, to Federal and State authorities.</p> <p>This STANDARD is not met as evidenced by: Based on record review, review of policies and procedures (P&P), lack of documentation, and interview the facility failed to establish and define the specific criteria and parameters to promptly identify a blood or blood product transfusion reaction in 4 of 4 facility P&P reviewed. Findings: 1. Review of 2020 and 2021 laboratory blood bank transfusion records revealed no transfusion reactions identified in the two years. 2. Review of facility P&P related to blood product transfusions and transfusion reactions revealed no definition of the specific criteria and the parameters that indicate a possible transfusion reaction in all 4 reviewed. a. "Investigation of Adverse Transfusion Reactions" states all unfavorable events and adverse outcomes must be reported to the laboratory and names the different types of transfusion reactions. No specific criteria or defined parameters that indicate a transfusion reaction could be located. b. "Administration of Blood to Patients" states that the recipient must be closely observed for signs and symptoms of adverse reactions. No definition of the specific criteria and the parameters that indicate a possible transfusion reaction could be located. c. "Blood Administration" describes the process</p>

of transfusing blood products and the time frame for taking recipient vital signs. No definition of the specific criteria and the parameters that indicate a possible transfusion reaction could be located. d. "Blood Reaction" details the process to take if a transfusion reaction is suspected. No definition of the specific criteria and the parameters that indicate a possible transfusion reaction could be located. 3. An interview with the general supervisor, 3/1/2022 at approximately 1:30 PM, confirmed that no defined parameters and specific criteria to identify a possible blood transfusion reaction could be located in the facility P&P.

D3035

RETENTION REQUIREMENTS
CFR(s): 493.1105(a)(3)(ii)

In addition, the laboratory must retain immunohematology records, blood and blood product records, and transfusion records as specified in 21 CFR 606.160(b)(3)(ii), (b)(3)(iv), (b)(3)(v), and (d).

This STANDARD is not met as evidenced by:
Based on record review, lack of documentation, policies and procedures (P&P), and interview the laboratory failed to retain complete immunohematology records for 5 of 7 patient transfusion records reviewed. Findings: 1. Review of the 7 emergency release patient records from 2020 and 2021 identified the following 5 patient records with a lack of documentation : 3/23/2020 4 units documented on the emergency release form, no transfusion forms could be located for 2 of the 4 units 8/20/2020 2 units documented on emergency release form, no transfusion forms could be located for the 2 units 10/4/2020 2 units documented on emergency release form, no transfusion forms could be located for the 2 units 2 more units written in the transfusion log book, no transfusion forms could be located 1/7/2021 7 units listed on the emergency release form, no transfusion forms could be located for the 7 units 4 units of FFP written in the transfusion log book, no transfusion forms could be located 6/7/2021 1 unit documented on emergency release form, no transfusion form could be located 2 more units written in the transfusion log book, no transfusion form could be located for 1 of the 2 2. Review of P&P for the laboratory blood bank identified "Administration of Blood to Patients" which states a transfusion record must be completed for each unit of blood transfused. No written process for the completion and retention of patient transfusion records could be located. Refer to D5403. 3. An interview with the general supervisor, on 3/1/2022 at approximately 4:00 PM, confirmed the findings.

D5217

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(c)(1)

At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:
Based on record review, lack of documentation, and interview the laboratory failed to verify the accuracy for three of three CMS unregulated analytes in 2020 and 2021. Findings: 1. Review of proficiency testing records revealed that KOH, Wet Prep, and DAT testing had no documentation of enrollment in a commercial proficiency testing program. 2. Review of Subpart I (regulated analytes) identified KOH, Wet Prep, and DAT testing are not classified by CMS as regulated analytes. 3. No documentation of

biannual accuracy verification of KOH, Wet Prep, and DAT testing could be located for 2020 and 2021. 4. An interview with the general supervisor, 3/1/22 at approximately 10:00 AM, confirmed that KOH, Wet Prep, and DAT testing had no commercial PT and verification of accuracy was not performed for 2020 and 2021.

D5403

PROCEDURE MANUAL

CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on review of policies and procedures (P&P), record review, a lack of documentation, and interview the laboratory failed to define (6) the reportable ranges for 46 of 51 analytes tested in Chemistry and failed to establish (13) the process for recording transfusions of blood and blood products into the permanent patient record in Immunohematology. Findings: Chemistry 1. Review of P&P identified the current "Test Menu" and "Assay Range" documents for the chemistry department listed different test methods utilized by the laboratory. Refer to D5809. 2. Review of "Assay Range" document revealed no defined upper reportable range limit for 46 of the 51 analytes tested on the Siemens Dimension EXL 200 chemistry analyzers. 3. An interview with the general supervisor, 3/2/22 at approximately 10:00 AM, confirmed the findings. Immunohematology 1. Review of blood bank P&P revealed no written procedure for the process of documenting and retaining the records for each unit of blood and blood products transfused into the laboratory permanent patient blood bank record. 2. Review of patient transfusion records identified 5 of 7 had a lack of required documentation. Refer to D3035. 3. An interview with the general supervisor, 3/2/22 at approximately 8:00 AM, confirmed no P&P could be located for the process.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:
Based on review of policies and procedures (P&P), blood bank transfusion records, and interview the laboratory failed to (a) establish a process to monitor, assess, and correct problems identified in transfusion medicine. Specifically: 1) Ensuring all blood bank documentation is accurate and complete for transfusions of each blood and blood product. Refer to D5403 and D3035. 2) Ensuring established P&P for the process of documenting and retaining records for each unit of blood and blood product transfused into the laboratory permanent patient blood bank record. Refer to D5403. 3) Ensuring the facility has established P&P that define the specific criteria and the parameters of vital signs that could identify possible transfusion reactions. Refer to D3025.

D5809

TEST REPORT
CFR(s): 493.1291(e)

The laboratory must, upon request, make available to clients a list of test methods employed by the laboratory and, as applicable, the performance specifications established or verified as specified in 493.1253. In addition, information that may affect the interpretation of test results, for example test interferences, must be provided upon request. Pertinent updates on testing information must be provided to clients whenever changes occur that affect the test results or interpretation of test results.

This STANDARD is not met as evidenced by:
Based on review of policies and procedures (P&P) and interview, the laboratory failed to provide an accurate list of the current test methods for 3 of the 5 laboratory departments. 1. Review of P&P identified "Test Menu" that listed the following: Chemistry 58 tests Hematology 5 tests Microscopy 5 tests Serology 7 tests Blood Bank 5 tests 2. An interview with the general supervisor, 3/1/2022 at approximately 2:00 PM, revealed the laboratory no longer performed gram stains and fern tests (Microscopy), urine calcium (Chemistry), and spinal cell counts (Hematology) testing that were listed on the current test menu.