

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0397019	(X3) Date Survey Completed 12/02/2020
Name of Provider or Supplier Burnett Medical Center	Street Address, City, State 257 W St George Ave, Grantsburg, WI	
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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Item 1: Based on surveyor review of proficiency testing (PT) and other laboratory records and interview with the technical consultant, the laboratory did not verify the accuracy of potassium hydroxide (KOH) testing performed on skin samples twice annually in 2019 or 2020. Findings include: 1. Review of PT records from 2019 and 2020 showed no evidence of evaluation of KOH testing of skin samples. 2. Review of other laboratory records showed no evidence of accuracy verification of KOH testing of skin samples. 3. Interview with the technical consultant on December 1, 2020 at 10:55 AM confirmed the laboratory performed KOH testing of skin samples. Further interview confirmed the laboratory had not developed a process to verify the accuracy of this testing twice annually. Item 2: Based on surveyor review of proficiency testing (PT) and other laboratory records and interview with the general supervisor, the laboratory did not verify the accuracy of body fluid cell differentials twice annually in 2019 or 2020. Findings include: 1. Review of PT records from 2019 and 2020 showed no evidence of evaluation of body fluid cell differentials. 2. Review of other laboratory records showed the laboratory performed three body fluid cell differentials on patient samples in 2020. Further review showed no evidence of accuracy verification of body fluid cell differentials. 3. Interview with the general supervisor on December 2, 2020 at 11:15 AM confirmed the laboratory performed body fluid cell differentials. Further interview confirmed the laboratory had not developed a process to verify the accuracy of this testing twice annually. This is a repeat deficiency previously cited on June 9, 2010.</p>
D5449	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 surveyor review of immunohematology quality control records and laboratory procedures, and interview with the general supervisor, the laboratory did not test a negative control material with Search-Cyte Reagent Blood Cell II each day of patient testing since August 27, 2018 and did not test Anti-D reagent with a negative control material since August 12, 2019. Findings include: 1. Review of the immunohematology "Daily / Weekly QC Log" from the week of August 5, 2019 showed the Search-Cyte Reagent Blood Cell II was only tested with Anti-D reagent for a positive reaction. The instructions on the form (revised August 27, 2018) did not identify a negative control material for Search-Cyte Reagent Blood Cell II. Review of the immunohematology "Daily / Weekly QC Log" from the week of November 9, 2020 (revised August 12, 2019) showed only positive reactions for Search-Cyte Reagent Blood Cell II and Anti-D reagents. The instructions directed testing personnel to test the Search-Cyte Reagent Blood Cell II with Anti-D and Anti-c reagent; both reactions were expected to be positive. The form also directed testing personnel to test Anti-D reagent with Search-Cyte Reagent Blood Cell I and II and showed both expected results as positive. 2. Review of the laboratory procedure, "Rh (D) blood grouping", showed the Quality Control section stated, the Anti-D reagent "should be confirmed each day of testing with red blood cells known to be negative and positive for the relevant antigen". 3. Interview with the general supervisor on December 2, 2020 at 11:30 AM confirmed the laboratory's quality control program did not ensure testing personnel tested Anti-D reagent (since August 12, 2019) and Search-Cyte Reagent Blood Cells II (since August 27, 2018) with a negative control material each day of testing. This is a repeat deficiency previously cited on June 9, 2010.

D5785

CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(3)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.

This STANDARD is not met as evidenced by:

Based on surveyor review of laboratory records and interview with the general supervisor, the laboratory did not take and document corrective actions when the room humidity was not within acceptable limits on 25 of 31 days in October 2020. Findings include: 1. Review of the laboratory's "Temp Log" from October 2020 showed the acceptable room humidity range is from 20 to 80 percent (%). Further review showed testing personnel documented humidity less than 20% (Lo) on October 2 - 5, 7 - 8, 10, and 14 - 31, 2020. No evidence of corrective actions taken is present on the log. 2. Interview with the general supervisor on December 2, 2020 at 10:15AM confirmed the laboratory did not take or document corrective actions for the unacceptable humidity readings in October 2020.

D6085

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(3)

The laboratory director must ensure that the test methodologies selected have the capability of providing the quality of results required for patient care.

This STANDARD is not met as evidenced by:

Based on surveyor review of manufacturer's instructions, laboratory logs, and interview with the general supervisor and technical consultant, the laboratory director did not ensure the Sofia RSV (Respiratory Syncytial Virus) test could provide the quality of results required for testing adult patients. Findings include: 1. Review of the manufacturer's instructions for the Quidel Sofia RSV test showed the intended use of the test is limited to "use as an aid in the rapid diagnosis of acute RSV infections in pediatric patients." The manufacturer's instructions also state the CLIA complexity is "moderate for pediatric patients seven to less than 19 years of age." Further review shows the manufacturer's performance characteristics were determined on patients less than 19 years of age. 2. Review of the "RSV Patient Test Result Log" from February 3 through April 3, 2020 showed of the ten patients tested, two were older than nineteen years and three records did not include the patient's date of birth. Patient number / date of birth / test date Patient 1 / May 11, 1965 / March 14, 2020 Patient 2 / August 9, 1948 / April 3, 2020 Patient 3 / not known / February 3, 2020 Patient 4 / not known / February 20, 2020 Patient 5 / not known / March 13, 2020 3. Interview with the general supervisor on December 2, 2020 at 11:15 AM confirmed the laboratory tested patients that were older than nineteen years of age using the Sofia RSV test, outside of the intended use of the test system. Further interview confirmed the laboratory had not evaluated the use of the Sofia RSV test for adult patients to ensure the Sofia RSV test had the capability of providing the quality of results required for adult patient care. This is a repeat deficiency previously cited on June 9, 2010.

D6093

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on surveyor review of manufacturer's instructions and laboratory records, and interview with the general supervisor and technical consultant, the laboratory director did not ensure the quality control (QC) program for the Sofia RSV (Respiratory Syncytial Virus) test was established and maintained to meet the regulatory requirements for a non-waived test system. Findings include: 1. Review of the manufacturer's instructions for the Quidel Sofia RSV test showed the test complexity is waived only when performed on children less than seven years of age. 2. The February 3 through April 3, 2020 "RSV Patient Test Result Log" showed of the ten patients tested, three were older than seven years and three records did not include the patient's date of birth. The log shows the laboratory used test lot number 8360540 for testing recorded on the log. 3. Review of quality control records for the Sofia RSV test on the "Kit QC" logs showed the laboratory only tested QC material on the following days in 2020 for the identified test lot numbers. January 31, 2020 / lot 9074641 May 29, 2020 / lot 705688 November 10, 2020 / lot 706038 Laboratory

personnel performed QC testing on lot 8360540 on July 19, 2019. 4. Interview with the general supervisor on December 2, 2020 at 11:15 AM confirmed the laboratory tested patients that were older than seven years of age using the Sofia RSV test. Interview with the technical consultant on December 2, 2020 at 12:00 PM confirmed the requirements for QC testing were not established or maintained to meet the QC requirements for non-waived testing.