

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  44D0688412	<b>(X3) Date Survey Completed</b>  07/16/2018
<b>Name of Provider or Supplier</b>  Dyersburg Family Walk In Clinic	<b>Street Address, City, State</b>  8633 Hwy 22, Dresden, TN	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5006</b>	<p>MYCOLOGY CFR(s): 493.1203</p> <p>If the laboratory provides services in the subspecialty of Mycology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1263, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: The laboratory failed to follow written policies to assess testing personnel for the whiff test (Refer to D5209); failed verify at least twice a year, the accuracy of the whiff test (Refer to D5217); failed to have a procedure for the whiff test (Refer to D5401); and, failed to perform verification of performance specifications for the whiff test (Refer to D5421).</p>
<b>D5209</b>	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the laboratory personnel records, one patient final report, interview with testing personnel number one and the technical consultant, the laboratory failed to follow written policies to assess testing personnel for using potassium hydroxide (KOH) for the whiff test, in 2018. The findings include: 1) Observation of the laboratory on July 16, 2018 at 1:40 p.m. revealed a bottle of potassium hydroxide (KOH) lot number 1735206 expiration date 12-18-18 , open date 2-6-18, in use for patient testing. 2) Review of the laboratory personnel</p>

records revealed no personnel were assessed for the use of KOH for patient testing. 3) Review of patient number one final report revealed on June 15, 2018 the Whiff test was reported as negative. 4) Interview on June 16, 2018 at 1:50 p.m. with testing personnel number one confirmed the family nurse practitioner uses the KOH to perform the Whiff test for patient testing. 5) Interview on June 16, 2018 at 2:30 p.m. with the technical consultant confirmed no personnel were assessed for the Whiff testing using KOH.

**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 observation of the laboratory, review of all the laboratory records, one patient final report, interview with testing personnel number one and the technical consultant, the laboratory failed verify at least twice a year, the accuracy for using potassium hydroxide (KOH) for the whiff test, in 2018. The findings include: 1) Observation of the laboratory on July 16, 2018 at 1:40 p.m. revealed a bottle of potassium hydroxide (KOH) lot number 1735206 expiration date 12-18-18 , open date 2-6-18, in use for patient testing. 2) Review of the laboratory personnel records revealed no twice per year accuracy for the use of KOH for patient testing. 3) Review of patient number one final report revealed on June 15, 2018 the Whiff test was reported as negative. 4) Interview on June 16, 2018 at 1:50 p.m. with testing personnel number one confirmed the family nurse practitioner uses the KOH to perform the Whiff test for patient testing. 5) Interview on June 16, 2018 at 2:30 p.m. with the technical consultant confirmed no accuracy verification twice per year for the Whiff testing using KOH was performed.

**D5401**

**PROCEDURE MANUAL**  
CFR(s): 493.1251(a)

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:  
Based on observation of the laboratory, review of the laboratory procedure manual, one patient final report, interview with testing personnel number one and the technical consultant, the laboratory failed to have a procedure for using potassium hydroxide (KOH) for the whiff test, in 2018. The findings include: 1) Observation of the laboratory on July 16, 2018 at 1:40 p.m. revealed a bottle of potassium hydroxide (KOH) lot number 1735206 expiration date 12-18-18 , open date 2-6-18, in use for patient testing. 2) Review of the laboratory procedure manual revealed no procedure for using KOH for the Whiff test. 3) Review of patient number one final report revealed on June 15, 2018 the Whiff test was reported as negative. 4) Interview on June 16, 2018 at 1:50 p.m. with testing personnel number one confirmed the family

nurse practitioner uses the KOH to perform the Whiff test for patient testing. 5) Interview on June 16, 2018 at 2:40 p.m. with the technical consultant confirmed no procedure for the Whiff testing using KOH.

**D5417**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**  
CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on observation of the laboratory, review of the complete blood count (CBC) quality control (QC) records and interview with the technical consultant, the laboratory failed to ensure the CBC QC was not in use after the expiration date, in October and November 2017. The findings include: 1) Observation of the laboratory on July 16, 2017 at 1:40 p.m. revealed the Drew 3 CBC instrument in use for patient testing. 2) Review of the October and November 2017 CBC QC records revealed lot number 0717 expiration date 10-05-17 was in use until 11-28-17. 3) Interview on July 16, 2017 at 3:00 p.m. with the technical consultant confirmed the CBC QC records have the lot number 0717 with expiration date 10-05-17 in use until 11-28-17.

**D5421**

**ESTABLISHMENT AND VERIFICATION OF PERFORMANCE**  
CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on observation of the laboratory, review of all the laboratory records, one patient final report, interview with testing personnel number one and the technical consultant, the laboratory failed to perform verification of performance specifications for using potassium hydroxide (KOH) for the whiff test, in 2018. The findings include: 1) Observation of the laboratory on July 16, 2018 at 1:40 p.m. revealed a bottle of potassium hydroxide (KOH) lot number 1735206 expiration date 12-18-18, open date 2-6-18, in use for patient testing. 2) Review of all the laboratory records revealed no accuracy and precision verification of performance specifications records for the Whiff testing using KOH were available for review. 3) Review of patient number one final report revealed on June 15, 2018 the Whiff test was reported as negative. 4) Interview on June 16, 2018 at 1:50 p.m. with testing personnel number one confirmed the family nurse practitioner uses the KOH to perform the Whiff test for patient testing. 5) Interview on June 16, 2018 at 2:30 p.m. with the technical consultant confirmed no verification of performance specification was performed for the Whiff testing using KOH.