

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0950892	(X3) Date Survey Completed 09/12/2018
Name of Provider or Supplier Buffalo Medical Group	Street Address, City, State 425 Essjay Road, Williamsville, NY	
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
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor's review of current refrigerator temperatures records, BBL Mycosel & Acu-DTM Quality control (QC) records and an interview with the physician assistant, the laboratory failed to retain temperature charts and BBL assay sheets for Acu-DTM & Mycosel Agar fungal media, QC records, physical characteristics & sterility for the media. FINDINGS: The physician assistant confirmed on September 12, 2018 at approximately 2:15 PM, surveyor's findings that the laboratory failed to retain the following documents and records: a. 2017 refrigerator temperature charts for the refrigerator used to store the fungal media. b. the current Mycosel & Acu-DTM manufacturer's assay sheets for the fungal media. c. the QC records, physical characteristics and sterility for the current lot in use (# M1540417 expiration date 4/19/19) for the Acu-DTM media.</p>
D5209	<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 surveyor's review of laboratory records and an interview with the physician</p>

	<p>assistant, the laboratory failed to establish a comprehensive written policy and procedure that includes the six required components that assess testing personnel's competency. The six required components are: 1. direct observation of routine patient test performance, including preparation, specimen handling and testing; 2. monitoring the recording and reporting of test results; 3. review of intermediate results of worksheets, quality control records, proficiency testing results, and preventive maintenance records; 4. direct observation of performance of instrument maintenance and function checks; 5. assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and, 6. assessment of problem solving skills.</p>
<p>D5291</p>	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>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 general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on a lack of quality Assessment (QA) policies and procedures and confirmed in an interview with the physician assistant, at the time of this survey, the laboratory failed to establish and follow a written QA policy and procedure for an ongoing mechanism to monitor, assess, and when indicated correct problems that may occur in the laboratory testing.</p>
<p>D5309</p>	<p>TEST REQUEST CFR(s): 493.1241(e)</p> <p>If the laboratory transcribes or enters test requisition or authorization information into a record system or a laboratory information system, the laboratory must ensure the information is transcribed or entered accurately.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor's review of test requisitions, test reports and confirmed in an interview with the physician assistant, the laboratory failed to have a system in place to ensure that the individual(s) entering the patient data into the Electronic Medical Record (EMR) is transcribing it correctly.</p>
<p>D5400</p>	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by:</p>

	<p>Based on surveyor's review of records and an interview with the physician assistant the laboratory failed to ensure that the: 1. current laboratory director sign and date the Dermatology Procedure manual, refer to D5407; 2. laboratory follow the manufacturer's temperature requirements for the fungal media, refer to D5413; 3. laboratory discontinue the use of the expired fungal Mycosel media, refer to D5417; 4. laboratory follow the established microscope maintenance policy, refer D5429; 5. laboratory establish a Individualized Quality Control Plan (IQCP), refer to D5441; 6. laboratory perform and document quality control for the fungal media, refer to D5445.</p>
<p>D5407</p>	<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 surveyor's review of the Dermatology Procedure manual and confirmation by the physician assistant, at the time of this survey, the current laboratory director failed to approve and sign the Dermatology Procedure manual.</p>
<p>D5413</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on a surveyor's review of laboratory's temperature records and an interview with the physician assistant, the laboratory failed to follow the manufacturer's temperature requirement for the fungal media. FINDINGS: 1. The physician assistant confirmed on September 12, 2018 at approximately 2:30 PM the surveyor's findings that the laboratory failed to monitor and document the room temperatures as required by the manufacturer's criteria, for the storage of the fungal media and the incubation temperature for the patients' fungal cultures from January 1, 2017 through survey date. a. BBL Mycosel Agar and Acu-DTM media requires storage temperature 2-8 C and/or 36-46F b. BBL Mycosel Agar and Acu-DTM media requires incubation temperature 25-30 C and/or 68-86 F 2. The laboratory failed to monitor and document room temperature for each of the exam rooms where the Acu-DTM media is stored. 3. No documentation for room temperature for the incubation area was available at survey. 4. Approximately 100 patient samples were tested and reported during the above time frames.</p>
<p>D5417</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other</p>

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 a surveyor's observation of the fungal Mycosel media stored in the refrigerator and an interview with the physician assistant, the laboratory failed to discontinue the use of the expired fungal Mycosel media. FINDINGS: The physician assistant confirmed on September 12, 2018 at approximately 2:00 PM, the surveyor's findings 2 boxes of fungal Mycosel media lot # M 7291506 expiration date of 07/17 /2018 were observed in the refrigerator used to store the media.

D5429

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on surveyor's review of maintenance records, laboratory microscope maintenance polices and confirmed in an interview with the physician assistant, the laboratory failed to follow the established microscope maintenance policy and perform a cleaning of the microscope after each day of use for KOH, Wet Mount, Ecto-parasite and Tzanck smears from January 1, 2018 through survey date.

D5441

CONTROL PROCEDURES

CFR(s): 493.1256(a)(b)(c)(g)

(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on surveyor's review of QC records and confirmed in an interview with the physician assistant at the time of this survey, the laboratory failed to establish a Individualized Quality Control Plan (IQCP) to include Quality Control Plan (QCP), Risk Assessment (RA) plan and Quality Assessment (QA) policy for mycology testing.

D5445

CONTROL PROCEDURES

CFR(s): 493.1256(d)(1)(2)(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--
(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on surveyor's review of the fungal media QC records and an interview with the physician assistant, the laboratory failed to perform quality control on the fungal media from 01/01/2017 through survey date. FINDINGS: 1. The physician assistant confirmed on September 12, 2018, at approximately 2:10 PM, the surveyor' findings, that the laboratory failed to perform QC to ensure the reactivity of the media, physical characteristics and sterility for the fungal media: a. physical characteristics and sterility were not performed on the following lots: M 1511016 and M 1480116 expiration date 1/20/18 M 7291506 expiration date 7/17/18 M1540417 expiration date 4/19/19. c. the laboratory failed to check each batch and or shipment of fungal media using a control organism to verify the positive and negative reactivity of the media.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:
Based on surveyor's findings and an interview with the physician assistant, the laboratory director failed to provide overall management of the laboratory. The laboratory director failed to ensure that the: 1. QC program for mycology testing was maintained, refer to D6020; 2. QA program is followed for all phases of laboratory testing, refer to D6021; 3. Dermatology Procedure Manual was approved, signed and dated, refer D6031; 4. Annual 2017 competency evaluations for the testing personnel was performed and documented, refer to D6054.

D6020

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:
Based on the surveyor's review of the laboratory's quality control (QC) records and confirmed in an interview at the time of this survey with the physician assistant, the laboratory director failed to ensure that the QC program for mycology testing was

	<p>maintained to assure quality of laboratory services. Refer to :D5417, D5441 and D5445.</p>
D6021	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.</p> <p>This STANDARD is not met as evidenced by: Based on lack of QA records and an interview with the physician assistant, the laboratory director failed to follow the established QA procedures and identify issues, take and document remedial and corrective action for all phases of laboratory testing. Refer to D3031, D5291, D5309, D5413, D5417 and D5429.</p>
D6031	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's policy and procedure manuals and an interview with the physician assistant, the laboratory director failed to approve, sign and date the laboratory's manual for Dermatology testing. Refer to: D5407.</p>
D6054	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor's review of personnel records and an interview with the physician assistant, the laboratory director, acting as the technical consultant, failed to perform annual competency evaluations for the testing personnel for the 2017 calendar year. Refer to: D5209.</p>