

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D1082418	(X3) Date Survey Completed 02/05/2020
Name of Provider or Supplier Manchin Clinic South Llc	Street Address, City, State 181 Middletown Loop, Whitehall, 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
D2127	<p>HEMATOLOGY CFR(s): 493.851(d)</p> <p>Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory American Proficiency Institute (API) proficiency testing (PT) records and an interview with the technical consultant (TC) and testing personnel (TP), the laboratory failed to return PT results within the specified time frame resulting in a score of 0 for the 2019 API Hematology/Coagulation 3rd testing event. Findings: 1. A review of 2018 and 2019 API PT records identified a testing event score of 0 for the 2019 3rd Hematology/Coagulation testing event. 2. A review of the 2019 3rd Hematology/Coagulation testing event PT records identified the laboratory failed to submit the testing results within the specified time frame of API. A documented self-analysis of the laboratory results for the testing event was performed by the TC. 3. An interview with the TC and TP, on 02/05/2020 at approximately 9:30 AM, confirmed the findings.</p>
D5437	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii)</p>

Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:

Based on a review of written laboratory policies and procedures, calibration records, quality control (QC) records, and an interview with the technical consultant (TC) and testing personnel (TP), the laboratory failed to document and perform calibration of the ACT2 DIFF analyzer at the frequency specified by the manufacturer. Findings: 1. A review of written laboratory policies and procedures identified the frequency of calibration for the ACT2 DIFF as every 6 months, as a step in the process of resolving QC issues, and after major maintenance. 2. A review of 2018 calibration records revealed calibration of the ACT2 DIFF analyzer was documented on 02/07/2018. No documentation of calibration being performed on the ACT2 DIFF analyzer every 6 months in 2018 could be located. 3. A review of 2019 calibration records revealed calibrations performed on the ACT2 DIFF on 03/27/2019 and 12/27/2019. This is a 9 month span between calibrations in 2019. 4. A review of 2018 and 2019 QC records for the ACT2 DIFF analyzer identified numerous QC issues for January, February, and March of 2019. All three levels of QC exhibited data points out of range and corrective action for the out of range QC was to rerun the QC. No calibration was performed on the analyzer from 02/07/18 until calibration on 03/27/2019. 5. An interview with the TC and TP, on 02/05/2020 at approximately 8:45 AM, confirmed that only one calibration of the ACT2 DIFF analyzer occurred in 2018, no calibration was performed to resolve excessive QC issues, and the time between the 2 calibrations of 2019 exceeded the every 6 month time frame requirement.

D5439

CALIBRATION AND CALIBRATION VERIFICATION
CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

Based on a review of laboratory quality control (QC) records, calibration records, and

an interview with the technical consultant (TC) and testing personnel (TP), the laboratory failed to meet the calibration verification requirements (b)(3) for the ACT2 DIFF analyzer. Findings: 1. Review of 2018 and 2019 calibration records identified a failure to follow manufacturer instructions for the calibration of the ACT2 DIFF analyzer. Refer to D5437. 2. The lack of calibration every 6 months on the ACT2 DIFF analyzer in 2018 and 2019 is a failure to meet the calibration verification requirement for automated cell counters. 3. A review of 2018 and 2019 QC records for the ACT2 DIFF analyzer identified numerous QC issues for January, February, and March of 2019. All three levels of QC exhibited data points out of range and corrective action for the out of range QC was to rerun the QC. No calibration was performed on the analyzer from 02/07/18 until calibration on 03/27/2019. Refer to D5437. 4. An interview with the TC and TP, on 02/05/2020 at approximately 8:45 AM, confirmed the findings.

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 a review of laboratory quality control (QC) records, written laboratory policies and procedures, and an interview with the technical consultant (TC) and testing personnel (TP), the laboratory failed to consistently perform and document quality control in adherence to the established QC policy and procedure for the CliniTek Multistix 10 testing strips, Consult urine HCG cassette, and Afinon HgbA1C test system. Findings: 1. A review of 2018 and 2019 QC records identified a lack of quality control performed for the CliniTek Multistix 10 testing system. a. The written policy and procedure for external QC on the CliniTek Multistix 10 test strips for urinalysis stated "QC monthly and with each new rgt (reagent) strip vial opened." b. The last QC on the CliniTek Multistix 10 test strips documented was performed 04/24/2018 on lot 44462, expiration date of lot was 12/2018. c. The current lot in use of CliniTek Multistix 10 test strips had no documented QC and no external QC materials could be located in the laboratory. 2. A review of 2018 and 2019 QC records identified a lack of external quality control performed for the Consult Diagnostics HCG urine test system. a. The written laboratory policy and procedure states "external controls, included in kit, to be run with each new box opened and at least monthly." b. The last external QC on the Consult HCG cassette test documented was performed 05/29 (no year documented) on lot HCG7120139, expiration date of lot 12/31/2019. c. The current lot in use of Concul HCG cassette test had no documented QC. 3. A review of 2018 and 2019 QC records identified a lack of quality control performed for the Afinon HgbA1C testing system. a. The written laboratory policy and procedure states QC is to be performed on a monthly basis and with each new lot or shipment. b. The last QC on the Afinon HgbA1C test system documented was performed 12/27 (no

year documented) on lot CII10793444 and CII1095426, both with expiration dates of 06/2020. 4. A review of the 2018 and 2019 QC records for the CliniTek Multistix 10 test strips, Consult Diagnostics HCG urine test cassette, and the Afinon HgbA1C testing system identified a lack of consistent performance of QC and incomplete documentation. 5. An interview with the TC and TP, on 02/05/2020 at approximately 10:30 AM, confirmed the findings.

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 a review of written laboratory policies and procedures, quality control (QC) records, calibration records, proficiency testing (PT) records, a tour of the laboratory, and observation of the testing personnel (TP), the laboratory director (LD) failed to provide overall direction and management of the laboratory. Findings: 1. A review of 2018 and 2109 QC records identified an inconsistency in adherence to the QC policy for the CliniTek Multistix 10 reagent strips for urinalysis, the Consult urine HCG test cassette, and the Afinon HgbA1C test system. The review revealed lack of complete documentation of necessary information and the failure to perform QC on the specified schedule determined by the laboratory policy and procedure. Refer to D5441 and D6074. 2. No external quality control material for the CliniTek Multistix 10 reagent strips for urinalysis could be located in the laboratory for TP to perform the required QC on the current lot of reagent strips for urinalysis. 3. A review of 2018 and 2019 calibration records for the ACT2 DIFF analyzer identified that only 1 calibration was performed in the year 2018, resulting in extensive QC out of range issues. The 2 calibrations in 2019 exceeded the 6 month time frame between them as specified by the manufacturer. Refer to D5437 and D5439. 4. A review of laboratory 2018 and 2019 American Proficiency Institute PT records identified a failure to submit testing event results before the specified deadline for the 3rd event of 2019, resulting in an unsuccessful score of 0 for the testing event. Refer to D2127. 5. A tour of the laboratory and observation of the laboratory process confirmed there was only 1 TP responsible for all the daily operations of the laboratory which included all aspects of the general laboratory systems, preanalytic systems, analytic systems, and postanalytic systems, and the process of patient workload which included patient identification, sample collection, sample identification, and specimen referral. Refer to D6028 and D6074.

D6004

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(a)(b)

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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or

she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

Based on a review of laboratory written policies and procedures, quality control records, proficiency testing records, calibration records, and an observation of the laboratory processes, the laboratory director failed to provide effective administration of the laboratory, which includes ensuring accurate test performance and compliance with the regulations. Findings: 1. Refer to D6000.

D6017

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(ii)

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)(4)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory American Proficiency Institute (API) proficiency testing (PT) records, the laboratory director failed to (e)(4)(a) ensure that the results for the 3rd API Hematology/Coagulation 2019 testing event were returned within the timeframe established by API, resulting in an unsuccessful score of 0 for the testing event. Findings: 1. Refer to D2127.

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 a review of laboratory quality control (QC) records, calibration records, written laboratory policies and procedures, and an interview with the technical consultant (TC) and testing personnel (TP), the laboratory director failed to ensure that the quality control program of the laboratory was maintained. Findings: 1. Refer to D5441, D5437, D5439 and D6072.

D6028

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(10)

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)(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart;

This STANDARD is not met as evidenced by:

Based on a review of written laboratory policies and procedures, quality control (QC) records, calibration records, proficiency testing (PT) records, a tour of the laboratory, and observation of the testing personnel (TP), the laboratory director (LD) failed to properly supervise the overall operation of the laboratory by ensuring adherence to the applicable regulations and (e)(10) employing a sufficient number of testing personnel for the patient workload. Findings: 1. A review of 2018 and 2109 QC records identified an inconsistency in adherence to the QC policy for the CliniTek Multistix 10 reagent strips for urinalysis, the Consult urine HCG test cassette, and the Afinon HgbA1C test system. The review revealed lack of complete documentation of necessary information and the failure to perform QC on the specified schedule determined by the laboratory policy and procedure. Refer to D5441. 2. A review of 2018 and 2019 calibration records for the ACT2 DIFF analyzer identified that only 1 calibration was performed in the year of 2018., resulting in extensive QC out of range issues. The 2 calibrations in 2019 exceeded the 6 month time frame between them as specified by the manufacturer. Refer to D5437 and D5439. 3. A review of laboratory 2018 and 2019 American Proficiency Institute PT records identified a failure to submit testing event results before the specified deadline for the 3rd event of 2019, resulting in an unsuccessful score of 0 for the testing event. Refer to D2127. 4. A tour of the laboratory and observation of the laboratory process confirmed there was only 1 TP responsible for all the daily operations of the laboratory. This included the daily monitoring of environmental conditions, running of QC program for test methods, troubleshooting, calibrations, parallel testing of QC lots, daily/weekly/monthly maintenance, inventory of supplies, testing of proficiency testing events, and all the required documentation. In addition, the TP was also observed being responsible for the patient workload, which included patient identification, sample collection, sample identification, specimen preparation, specimen storage, and specimen referral for the daily patient workload requiring laboratory testing.

D6072

TESTING PERSONNEL RESPONSIBILITIES

CFR(s): 493.1425(b)(3)

Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed.

This STANDARD is not met as evidenced by:

Based on a review of written laboratory policies and procedures, quality control (QC) records, calibration records, and an interview with testing personnel (TP), the moderate complexity testing personnel did not adhere to the established laboratory QC and calibration processes and failed to perform and document the required actions. Findings: 1. A review of 2018 and 2019 QC records, and the written policies and procedures of the laboratory, identified TP did not adhere to the laboratory QC policies involving the CliniTek Multistix 10 test strips, Consult urine HCG test cassette, and Afinon HgbA1C test system. QC was not performed at the frequency required and the documentation of the QC that was performed was incomplete. Refer

to D5441. 2. A review of 2018 and 2019 calibration records identified TP did not adhere to the required calibration schedule of the ACT2 DIFF. Refer to D5437 and D5439. 3.. A review of 2018 and 2019 QC records for the ACT2 DIFF analyzer identified numerous QC issues for January, February, and March of 2019. All three levels of QC exhibited data points out of range and corrective action for the out of range QC was to rerun the QC. No calibration was performed on the analyzer from 02/07/2018 until calibration on 03/27/2019. 5. An interview with the TC and TP, on 02/05/2020 at approximately 8:30 AM, confirmed that only one calibration of the ACT2 DIFF analyzer occurred in 2018, no calibration was performed to resolve excessive QC issues, and the time between the 2 calibrations of 2019 exceeded the every 6 month time frame requirement. An interview with the TC and TP, on 02/05/2020 at approximately 10:30 AM, confirmed the QC for the CliniTek Multistix 10 test strips, Consult urine HCG test cassette, and the Afinon HgbA1C test system was not being performed according to established policies and documentation was incomplete.