| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 52D2126465 | 01/23/2018 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Fmccp North Hills Health Center | W129 N7055 Northfield Drive, 1st Floor, Rm 1064, Menomonee Falls, 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 |
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| **D3037** | RETENTION REQUIREMENTS<br>CFR(s): 493.1105(a)(4)<br><br>Proficiency testing records. Retain all proficiency testing records for at least 2 years.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of proficiency testing (PT) records and interview with the general supervisor, the laboratory did not retain records from the serum pregnancy 2017 second PT event. Findings include: 1. Review of PT records showed no evidence of testing records, signed attestation statements, PT results and scores from the PT provider, or documentation of review for the serum pregnancy event two of 2017. 2. Interview with the general supervisor, staff A, at 10:45 AM on January 23, 2018 confirmed laboratory testing records and documented review of results could not be located for this PT event. |
| **D5403** | PROCEDURE MANUAL<br>CFR(s): 493.1251(b)<br><br>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 |

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| | 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.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of the KOH (Potassium hydroxide) procedure, observation in the laboratory, and interview with the general supervisor, the KOH procedure does not provide step by step instructions that can be performed in this laboratory. Findings include: 1. Review of the KOH procedure shows the KOH slide preparation is to be heated over a flame in a safety hood. 2. Observation of the laboratory on January 23, 2018 at 10:45 AM reveals the laboratory does not have a safety hood available. 3. Interview with the general supervisor, staff A, on January 23, 2018 at 2:15 PM confirms this laboratory cannot perform the KOH procedure as specified in the procedure. |
| **D5417** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(d)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor observation in the laboratory and interview with the general supervisor, the KOVA Stain available for patient testing was expired. Findings include: 1. Observation of the reagents near the microscope in the lab on January 23, 2018 at 10:00 AM revealed the KOVA stain (lot number K300942) expired on August 31, 2017. 2. Interview with the general supervisor , staff A, on January 23, 2018 at 10: 00 AM confirmed the stain was expired and was available for use in testing patient specimens. |
| **D5439** | CALIBRATION AND CALIBRATION VERIFICATION<br>CFR(s): 493.1255(b)<br><br>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 |

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| | 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.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of Individualized Quality Control Plans (IQCP) for the Piccolo analyzer and laboratory records, and interview with the general supervisor, the laboratory did not perform calibration verification every six months as required in the laboratory's IQCP. Findings include: 1. Review of the IQCPs for Piccolo chemistry panels showed the laboratory requires calibration verification twice annually. 2. Review of records showed no documented calibration verification performed after the initial verification studies. 3. Interview with the general supervisor, staff A, on January 23, 2018 at 12:30 PM confirmed the laboratory had not performed calibration verification since the initial verification of the Piccolo performance specifications in May 2017, and had not met their requirement for performance of calibration verification on the four panels tested with the Piccolo analyzer. |
| **D5449** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(3)(ii)(g)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of laboratory procedures, quality control (QC) records, and interview with the general supervisor, the laboratory performs serum pregnancy QC monthly and had not performed a negative and positive control each day of patient testing since the laboratory opened. Findings include: 1. Review of the laboratory serum pregnancy procedure showed the laboratory performs external control testing once each month and with each shipment. The procedure does not reference an equivalent quality testing procedure. 2. Review of QC records shows no indication that external QC is performed with patient testing. 3. Interview with the general supervisor, staff A, on January 23, 2018 at 2:30 PM confirms the laboratory has not tested two levels of external controls each day of patient serum pregnancy testing. Further interview reveals the laboratory has performed four serum pregnancy patient tests since testing was initiated. |
| **D5471** | CONTROL PROCEDURES<br>CFR(s): 493.1256(e)(1)(g)<br><br>(e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and |

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| | negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of quality control (QC) testing on the Piccolo analyzer and interview with the general supervisor, a new lot number of the Piccolo hepatic panel was put into use on November 27, 2017 and controls were not tested to verify the test system was functioning prior to testing and reporting patient samples. Findings include: 1. Review of QC records for the Piccolo hepatic panel shows reagent lot 7192AB3 was in use in November. Records for December show reagent lot 7304AB3 was in use on December 1. QC records do not show when the lot number change occurred in November. 2. Interview with the general supervisor, staff A, on January 23, 2018 at 1:00 PM revealed the new lot was started on November 27, 2017 and five patient samples were tested with the new lot number before the laboratory tested controls to demonstrate the reagents were functioning as expected. |
| **D6085** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(3)<br><br>The laboratory director must ensure that the test methodologies selected have the capability of providing the quality of results required for patient care.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of the validation studies performed for the chemistry and hematology analyzers and interview with the general supervisor, the laboratory director did not ensure all test methodologies on the chemistry analyzer were evaluated to ensure the test system was capable of providing quality results and did not verify reference ranges for testing on either analyzer as required at 493.1253(b)(1)(ii), Establishment and Verification of Performance Specifications. Findings include: 1. Review of the Piccolo analyzer validation studies shows the director signed the Validation Summary Review on May 12, 2017. Review of the records shows no evaluation of the Piccolo Hepatic Function Panel. The protocol overview lists the Basic Met, Liver panel plus, and the Metlac12 discs. Further review shows no evaluation of the reference range for any of the testing on the Piccolo analyzer. 2. Review of the validation studies for the hematology analyzer showed the 'Verify Reference Interval' item on the checklist is crossed off and marked 'NA', not applicable. Records showing evaluation of the reference ranges in use are not available. 3. Interview with the general supervisor, staff A, on January 23, 2018 at 12:30 PM confirmed no records were available showing evaluation of the Hepatic Function Panel on the Piccolo analyzer at this lab. Further interview confirmed the hepatic function test panel is available for patient testing. Additionally the general supervisor confirmed the verification procedures did not evaluate the adequacy of the reference ranges for this laboratory. |
| **D6089** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(4)(i)<br><br>The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part. |

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| | This STANDARD is not met as evidenced by:<br>Based on surveyor review of proficiency testing (PT) records and interview with the general supervisor, the laboratory director did not ensure PT samples were tested in the same manner as patient samples as required in Subpart H at 493.801. Findings include: 1. Review of proficiency testing records shows results from multiple panels for each chemistry sample tested on the Piccolo analyzer. The records show a basic metabolic panel was tested for each sample and that all tests on the basic metabolic sample are included on the other panels tested. 2. Interview with the general supervisor, staff A, at 10:45 AM on January 23, 2018 confirmed patient samples are tested with the panel or panels required to result the tests ordered and additional panels are not tested. Further interview confirmed the PT samples were tested differently than the patient samples. |
| **D6093** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(5)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of laboratory procedures, quality control (QC) records, and interview with the general supervisor, the laboratory director has not ensured the quality control program for testing on the hematology analyzer was established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. Findings include: 1. Review of the hematology analyzer procedure shows QC to evaluate both open and closed mode (mode to mode) is required daily. Further review of the procedure shows the number of controls required each day of testing is not specified. 2. Review of QC records show monthly review of QC was not documented prior to January 2018. 3. Interview with the general supervisor, staff A, on January 23, 2018 at 2:00 PM confirmed the laboratory was enrolled in but unable to access Beckman Coulter's Interlaboratory Quality Assurance Program (IQAP) reports and that evaluation of these reports was not maintained through 2017. Further interview confirms the QC requirements for mode to mode evaluation outlined in the procedure have not been performed as required, and that the procedure does not define the number or frequency of QC testing required. |