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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br>45D1015161      | <b>(X3) Date Survey Completed</b><br>11/10/2021 |
| <b>Name of Provider or Supplier</b><br>Tch Family Medical Clinic   | <b>Street Address, City, State</b><br>104 North Beech Street, Woodville, TX |   |
| 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>   |
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| <b>D0000</b>              | Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended.  |
| <b>D3007</b>              | <p><b>FACILITIES</b><br/>CFR(s): 493.1101(b)</p> <p>The laboratory must have appropriate and sufficient equipment, instruments, reagents, materials, and supplies for the type and volume of testing it performs.</p> <p>This STANDARD is not met as evidenced by:<br/>Base on direct observation, review of CMS116, urinalysis reference manual, and confirmed in interview, the laboratory failed to have an appropriate centrifuge for one of one test: urine sediment analysis. 1. Direct observation in the laboratory at 13:30 hour on 11/10/2021 revealed a singular centrifuge with a fixed RPM of approximately 3,369. 2. Review of 'Preanalytical requirements of uinalysis' by Joris Delanghe and Marijn Speeckaert (published in Biochemia Medica 2014;24(1)89-104) Section 'Manual Methods' states: "A 5-minute centrifugation time at 400 g [RCF, relative centrifugal force (<math>g</math>) = <math>1.118 \times 10^{-5}</math> x radius (cm) x RPM (revolutions per minutes)] preferably at 4(degrees) C is necessary for optimal sediment concentration." 3. Review of the CMS116, Section VII 'PPM Testing' lists their estimated annual volume for PPM tests performed at 100. 4. Interview with the laboratory supervisor at 13:35 hours on 11/10/2021 in the hallway confirmed that the centrifuge in the laboratory was the one utilized for urine centrifugation for microscopic urine sediment analysis. Key: CMS - Centers for Medicare and Medicaid Services PPM - Provider Performed Microscopy RPM - Revolutions per minutes C - Celsius cm - centimeters</p> |
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**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 direct observation, review of laboratory policy, the CMS116, and confirmed in interview the laboratory failed to have a procedure in place for one of three tests: the processing and examination of microscopic urine sediment. 1. Direct observation of a microscope in the laboratory at 13:20 hours on 11/10/2021 and subsequent interview with the laboratory supervisor at 13:21 hours on 11/10/2021 revealed that providers perform microscopic urine sediment analysis when clinically indicated for patient. 2. Review of the laboratory's 'Routine Urinalysis' policy signed by the laboratory director on 9/12/2019, revealed that the laboratory did not have a procedure in place for the processing and examination of microscopic urine sediment. 3. Review of the CMS116, Section VII 'PPM Testing' lists their estimated annual volume for PPM tests performed at 100. 4. Interview with the laboratory supervisor in the hallway at 13:30 hours on 11/10/2021 confirmed they did not have a formal policy in place. Key: CMS - Centers for Medicare and Medicaid Services PPM - Provider Performed Microscopy

**D5403**

PROCEDURE MANUAL

CFR(s): 493.1251(b)

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 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.

This STANDARD is not met as evidenced by:

Based on review of laboratory hematology procedures, the CM116, and confirmed in interview, the laboratory did not have a procedure in place with instructions for corrective actions for when quality control (QC) results fail to meet the laboratory's criteria for acceptability for one of one hematology analyzers. 1. Review of the laboratory's 'Running Quality Control on the Cell-Dyn Emerald' signed by the

laboratory director on 10/23/2021 revealed that the laboratory failed to include instructions for corrective actions for when QC results failed to meet the laboratory's criteria for acceptability. 2. Review of the CMS116 lists their estimated annual volume for the Hematology specialty as 13,056. 3. Interview with the laboratory supervisor at 13:40 hours on 11/10/2021 in the hallway confirmed that the QC procedure available for the testing personnel did not include corrective actions for when the QC results fail to meet the laboratory's criteria for acceptability. Key: CMS - Centers for Medicare and Medicaid Services

**D5469**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(d)(10)(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-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:  
II. Based on review of the manufacturer's instructions, laboratory and patient test records from 2021, and confirmed in interview, the laboratory failed to establish the acceptable quality control range for three of three lots of quality control for the Abbott Cell-Dyn hematology analyzer. Findings included: 1. Review of the package insert for the Cell-Dyn 18 Plus Control under Performance Characteristics revealed "the mean assay values are derived from repetitive testing on several instruments operated and maintained according to the manufacturer's instructions; they do not necessarily apply to a single instrument. The recovery ranges are intended to reflect inter-laboratory and inter-instrument variability; thus, they are wider than the +/- 2 SD QC range for one instrument." 2. Review of the laboratory quality control records from 08/2021 to 11 /2021 revealed the laboratory performed quality control using the following lot numbers of Cell-Dyn 18 Plus Control with the corresponding acceptable ranges for the following five analytes. L1235, exp 12/10/2021 WBC: 2 - 2.8 RBC: 1.95- 2.35 HGB: 4.7 - 5.7 HCT: 14.3 - 18.3 PLT: 42 - 92 N1235, exp 12/10/2021 WBC: 7.5 - 9.5 RBC: 3.9 - 4.4 HGB: 10.8 - 12.2 HCT: 31.8 - 38.8 PLT: 166 - 236 H1235, exp 12/10 /2021 WBC: 15.6 - 20.6 RBC: 4.87 - 5.47 HGB: 14.8 - 16.8 HCT: 43.5 - 50.5 PLT: 357 - 527 3. Review of the laboratory records available revealed no documentation of the laboratory establishing the acceptable ranges for the above controls. 4. Random review of laboratory patient test records revealed the laboratory revealed the following 9 CBC patient samples. 8/24/2021: Sample ID 39190; 57690; 27130 9/03 /2021: Sample ID 36430 10/11/2021: Sample ID 175770 11/05/2021: Sample ID 12580 11/08/2021: Sample ID 156370; 78790 11/09/2021: Sample ID 27840 5. An interview with the laboratory supervisor on 11/10/21 at 1335 hours in the laboratory confirmed the above findings. 45469 Based on review of the Accu-Sed Plus controls instructions for use (IFU), quality control (QC) and patient log for June 2021 through October2021, and confirmed in interview, the laboratory failed establish its own

intralaboratory mean and standard deviation for two of two lot of ESR Control for the Excyte 10 Automated ESR Analyzer. 1. Review of the Accu-Sed Plus Normal ESR Control (ref DS-71002) section 'Expected Values' paragraph 2 stated: "Each laboratory should establish its own intralaboratory mean and standard deviation for each lot of ESR Control according to its own established procedures." 2. Review of the QC log showed an QC acceptable range that matched the package insert: Normal Control Lot 212010 Exp 2022-06-07 Excyte 10: Mean:7, Range 3-11 - put in use 6/7/2021 Abnormal Control Lot 213110 Exp 2022-06-07 Excyte 10: Mean 67, Range 49-85 - put in use 6/7/2021 Normal Control Lot 204101 Exp 9/29/2021 Excyte 10: Mean 7, Range 3-11 - Out of use 6/7/2021 Abnormal Control Lot 205110 Exp 9/29/2021 Excyte 10: Mean 63, Range 45-81 - Out of use 6/7/2021 3. Review of the patient testing log from June 2021 to October 2021 lists the following patient testing: June 2021 - 19 Patients tested: 6/1/2021 - Patient 55290, Patient 32790 6/2/2021 - Patient 60810 6/4/2021 - Patient 138400 6/7/2021 - Patient 126400, Patient 1320 6/8/2021 - Patient 12610, Patient 36140 6/11/2021 - Patient 36140 6/14/2021 - Patient 113680, Patient 26790 6/15/2021 - Patient 3950 6/21/2021 - Patient 26930 6/22/2021 - Patient 101580 6/24/2021 - Patient 16440, Patient 7310 6/28/2021 - Patient 129010 6/29/2021 - Patient 28950 6/30/2021 - Patient 152810 July 2021 - 9 Patients tested: 7/1/2021 - Patient 57750 7/5/2021 - Patient 163790 7/6/2021 - Patient 174760 7/7/2021 - Patient 191540 7/8/2021 - Patient 165980 7/9/2021 - Patient 152920 7/22/2021 - Patient 164910 7/27/2021 - Patient 62690 7/29/2021 - Patient 169300 August 2021 - 10 Patients tested: 8/3/2021 - Patient 97980 8/4/2021 - Patient 7610 8/5/2021 - Patient 76530 8/9/2021 - Patient 15310 8/13/2021 - Patient 88820 8/16/2021 - Patient 56150, Patient 100390, Patient 28750 8/20/2021 - Patient 6800 8/23/2021 - Patient 29700 September 2021 - 10 Patients tested: 9/7/2021 - Patient 100680 9/13/2021 - Patient 83630 9/14/2021 - Patient 98260 9/20/2021 - Patient 31230, Patient 74030, Patient 27840 9/22/2021 - Patient 171500 9/23/2021 - Patient 40920 9/27/2021 - Patient 36260 9/28/2021 - Patient 32340 October 2021 - 4 Patients Tested: 10/1/2021 - Patient 1320 10/5/2021 - Patient 3390 10/11/2021 - Patient 27840 10/27/2021 - Patient 21980 4. Interview with the laboratory supervisor at 13:10 hours on 11/10/2021 in the hallway confirmed that they have been using the QC ranges provided on the IFU, and not establishing their own laboratory means and ranges.