

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1089962	(X3) Date Survey Completed 10/03/2018
Name of Provider or Supplier Topcare Medical Group Inc	Street Address, City, State 9753 Webb Chapel Suite 900, Dallas, TX	
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
D0000	Based on the onsite survey conducted 10/02/2018 and 10/03/2018, this facility was found NOT to be in compliance with the CLIA regulations found at 42 CFR 493.1240 Preanalytic Systems 493.1403 Laboratory Director Moderate Complexity 493.1409 Technical Consultant Moderate Complexity The laboratory's failure to be in compliance with these regulations was found to pose IMMEDIATE JEOPARDY to the patients served by the laboratory. Technical Consultant 1 and 2 were informed at the exit conference on 10/03/2018 that the survey results were being sent to CMS Regional Office for evaluation and review, and that the CMS 2567 survey report would be sent by the CMS Regional Office.
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: The STANDARD is not met as evidenced by: Based on direct observation, review of manufacturer's instructions, and confirmed in interview, the laboratory failed to ensure the correct storage requirements for OSOM BVBlue Test kit. Findings: 1. During a tour of the laboratory on 10/03/2018 at 12:15 p.m., it was observed that the OSOSM BVBlue Test kit, Lot # B2394 expiration 04/2019 was stored at room temperature. Review of the manufacturer's package insert for OSOSM BVBlue Test storage requirements stated, "STORAGE AND STABILITY: Store the kit refrigerated, 2-8C (36-46F), out of direct sunlight." The laboratory did not store the above mentioned kit in refrigerated conditions (2-8C). 2. Technical Consultant (TC-1) acknowledged the OSOSM BVBlue Test kit was stored at room temperature and not refrigerated, as required on 10/03/2018 at 12:30 p.m.</p>

D2007

TESTING OF PROFICIENCY TESTING SAMPLES

CFR(s): 493.801(b)(1)

The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods

This STANDARD is not met as evidenced by:

Based on review of American Proficiency Institute (API) Proficiency Testing (PT) records, laboratory's CMS 209 form, and staff interview, laboratory failed to have documentation of rotating PT among testing personnel who routinely performed testing for 2 of 3 testing events in 2016 (2016 - 2), 3 of 3 testing events in 2017 (2017 -1, 2017 -2, 2017-3), and 3 of 3 testing events in 2018 (2018 - 1, 2018 -2) (hematology and endocrinology specialties). Findings: 1. Review of API PT records from 2016, 2017, and 2018 revealed Testing Person-6 (TP-6) tested the following events: Hematology: 2016 Testing Event 2 2017 Testing Events 1, 2, and 3 2018 Testing Events 1 and 2 Endocrinology: 2016 Testing Events 2 and 3 2017 Testing Events 1 and 3 2018 Testing Events 1, 2, and 3 2. Review of the laboratory's CMS 209 form revealed eight additional Testing Persons (TP-1, TP-2, TP-3, TP-4, TP-5, TP-7, TP-8, TP-9) listed as individuals who performed moderate complexity testing (hematology and endocrinology). TP-1 hire date: 04/06/2017 TP-2 hire date: 06/12/2018 (terminated 09/2018) TP-3 hire date: 01/21/2016 TP-4 hire date: 04/18/18 (terminated, no date provided) TP-5 hire date: 11/02/2017 TP-7 hire date: 06/20/2017 TP-8 hire date: 05/30/2018 TP-9 hire date: 04/18/18 The laboratory did not ensure hematology and endocrinology PT was rotated among the above additional Testing Persons listed. 3. During an interview on 10/02/2018 at 3:08 pm, Technical Consultant - 1 confirmed the above findings.

D3031

RETENTION REQUIREMENTS

CFR(s): 493.1105(a)(3)

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.

This STANDARD is not met as evidenced by:

I. Based on review of Qualigen daily quality control (QC) logs and in interview with staff, the laboratory failed to retain the expected value sheets for QC material used for Thyroid Stimulating Hormone (TSH) and Vitamin D tests for 3 of 3 lot number sets in 2016 and 2017. Findings included: 1. Review of "TSH DAILY QC RESULTS QUALIGEN" and "VITAMIN D DAILY QC RESULTS QUALIGEN" logs from 2016 and 2017 revealed documented lot numbers, ranges for acceptability, and daily results, as follows: Lot Number Level 1: 1605001; Lot Number Level 2: 1605002 - Date opened: 09/22/2016 and included TSH daily results from 09/22/2016 through 12/22/2016 and 03/30/2017 through 05/26/2017. Lot Number Level 1: 1603001; Lot Number Level 2: 1603001 - Date opened: 09/22/2016 and included Vitamin D daily results from 09/22/2016 through 12/02/2016. Lot Number Level 1: 1701033; Lot Number Level 2: 1701033 - Date opened: 05/09/2017 and included Vitamin D daily results from 05/19/2017 through 07/26/2017. The laboratory did not retain the expected value sheets to assess the ranges used for acceptability were consistent with manufacturer's. 2. During an interview on 10/03/2018 at 12:30 pm, Technical

Consultants #1 and #2 reviewed and confirmed the above findings. II. Based on review of Quidel Solana Influenza QC data and confirmed in interview with staff, the laboratory failed to retain the lot numbers of QC material used for Influenza A&B testing from 07/14/2018 through 10/01/2018. Findings included: 1. Review of Quidel Solana Influenza A&B QC daily printouts from 07/14/2018 through 10/01/2018 (29 days) revealed the printouts did not include lot numbers of the QC material used. The daily printouts included a tube number for "ID" and sections labeled "Lot:" and "Exp Date:" were blank. 2. During an interview on 10/02/2018 at 11:45 am, Technical Consultants #1 and #2 reviewed and confirmed the above findings. III. Based on review of the laboratory's procedure manual, hematology quality control (QC) data, corrective action, laboratory's portal, and confirmed in interview, the laboratory failed to retain all hematology QC data that were not within acceptable limits for 5 of 24 days reviewed in 07/2017 and from 07/02/2018 through 10/03/2018. Findings included: 1. Review of the laboratory's "QUALITY CONTROL POLICY" stated, "B. Quality Control record retention: All quality control, calibration, function checks and maintenance records must be retained for a period of two (2) years." 2. Review of the Coulter AcT Diff 2 analyzer QC data log ("WBC/DIFF CONTROL REVIEW" and "RBC/PLT CONTROL REVIEW") from 07/2017 revealed the following days QC was not within acceptable limits and the laboratory did not retain the daily instrument printouts: 07/11/2017 - QC Normal Level (Lot #075300, expiration date 08/18/18) was outside of limits at 7:40 am, outside limits at 7:43 am, and within limits at 8:22 am. QC High Level (Lot #087100) was outside of limits at 7:44 am, and within limits at 8:24 am. 07/13/2017 - QC Normal Level (Lot #075300, expiration date 08/18/18) was outside of limits at 7:38 am, and within limits at 7:44 am. QC High Level (Lot #087100) was outside of limits at 7:40 am, and within limits at 7:54 am. 07/14/2017 - QC Normal Level (Lot #075300, expiration date 08/18/18) was outside of limits at 7:46 am, outside limits at 8:05 am, and within limits at 8:21 am. QC High Level (Lot #087100) was outside of limits at 8:11 am, and within limits at 8:23 am. 07/20/2017 - QC Low Level (Lot #060100, expiration date 08/18/17) was outside of limits at 7:37 am, and within limits at 7:39 am. QC Normal Level (Lot #075300, expiration date 08/18/17) was outside of limits at 7:41 am, outside limits at 7:43 am, and within limits at 7:46 am. 07/25/2017 - QC Low Level (Lot #060100, expiration date 08/18/17) was outside of limits at 7:38 am, outside of limits at 7:50 am, and within limits at 7:51 am. QC Normal Level (Lot #075300, expiration date 08/18/17) was outside of limits at 7:44 am, and within limits at 7:47 am. Note: Corrective action taken was not documented for the above days QC was not within acceptable limits. Refer to D5781. 3. Review of Coulter AcT Diff 2 daily QC instrument printouts from 07/02/2018 through 10/03/2018 (total of 78 days) revealed there were no QC failures (outside acceptable limits), due to documents not being retained. According to Technical Consultant - 1 (TC-1) on 10/03/2018 at 10:30 am, the laboratory's practice was for Testing Persons to document corrective action in the portal (provided by TC-1 consulting company) when QC was outside acceptable limits; and to enter QC levels that are not within acceptable limits into the portal. Review of the laboratory's portal for QC from 07/02/2018 through 10/03/2018 revealed there were no QC failures entered and there was no documented corrective action. During an interview on 10/03/2018 at 10:30 am, TC-1 and TC-2 were asked to provide instrument monthly or lot number "WBC/DIFF CONTROL REVIEW" and "RBC/PLT CONTROL REVIEW" logs from 07/2018 through 10/2018. The laboratory was unable to provide the requested documentation for Lot #'s: 067700 (Low), 77700 (Normal), 87700 (High); 062600 (Low), 70300 (Normal), 82100 (High); 062400 (Low) (High and Normal Lot #'s not provided). The laboratory no longer printed the "WBC/DIFF CONTROL REVIEW" and "RBC/PLT CONTROL REVIEW" logs per lot number since implementation of the portal and the instrument only retained per lot number. The

laboratory's QC program could not be assessed to determine whether the program was detecting immediate error and that all QC procedures were being documented (QC failures, corrective action). 4. During an interview on 10/03/2018 at 10:50 am, Testing Person - 7 (TP-7) was asked how Coulter AcT Diff 2 QC failures were handled, she stated, "It is rare there are failures, but when there are I delete it and then I rerun (the QC) it. I keep the daily printouts in the binder." During an interview on 10/03/2018 at 10:52 am, TP-6 was asked how Coulter AcT Diff 2 QC failures were handled, he stated, "I will keep the passing one and throw away the failure (QC failure). I enter the passing one in the portal, I only keep the passing one." The laboratory staff was not retaining QC daily printouts with QC failures, not entering QC failures in the portal, and not documenting corrective action taken for QC failures.

D5300

PREANALYTIC SYSTEMS
CFR(s): 493.1240

Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, 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 preanalytic systems and correct identified problems as specified in 493.1249 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:
Based on direct observation, review of manufacturer's instructions, laboratory's procedure manual, instrument printouts, progress notes, test reports, and Quidel Solana studies, the laboratory failed to meet the requirements for the preanalytical systems as evidenced by: 1. The laboratory failed to ensure time of specimen collection was solicited to ensure specimens were tested on the Quidel Solana (Influenza A&B and Strep A) within the timeframe as defined by the manufacturer for patient testing. Refer to D5305. 2. The laboratory failed to ensure patient swabs were stored properly prior to testing for Influenza (A&B) on Quidel Solana for patients tested. Refer to D5311.

D5305

TEST REQUEST
CFR(s): 493.1241(c)

The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable.

This STANDARD is not met as evidenced by:

Based on direct observation, review of manufacturer's instructions, laboratory's procedure manual, instrument printouts, progress notes, test reports, and in interview with staff, the laboratory failed to ensure time of specimen collection was solicited to ensure specimens were tested on the Quidel Solana (Influenza A&B and Strep A) within the timeframe as defined by the manufacturer for 21 of 21 patients in 2018 (random sampling from 07/2018 through 10/2018). Finding included: 1. Review of Quidel manufacturer's instructions for Influenza A&B "SPECIMEN COLLECTION, STORAGE AND HANDLING" stated, "Nasal and nasopharyngeal specimens should be collected, transported, stored, and processed according to CLSI M41-A. Specimens should be stored at 2 to 8 (degrees) C (Celsius) until tested. Specimens collected in BD UTM (1- and 3 - mL), Remel M4 (3-mL), Remel M4RT (3-mL), Remel M5 (3-mL), and Remel M6 (3-mL) are stable at 2 to 8 C for up to 9 days. NOTE: Specimens collected in Copan eSwab transport media are stable at 2 to 8 C for up to 48 hours." The laboratory's procedure manual included the manufacturer's instructions, as their written policy. The laboratory used BD ESwab Transport System collection swabs for Influenza A&B testing. Review of Quidel manufacturer's instructions for Strep A test "SPECIMEN COLLECTION, STORAGE AND HANDLING" stated, "Analytical studies performed with contrived specimens containing Streptococcus pyogenes and Streptococcus dysgalactiae, near LOD (2x LOD) demonstrated that samples can be stored at 25C 2C for 2 days and then at 2C to 8C Solana Strep Complete Assay for up to 6 more days before testing or at -15C or -70C for up to 32 days before testing with the Solana Strep Complete Assay." The laboratory's procedure manual included the manufacturer's instructions, as their written policy. 2. During a tour of the laboratory on 10/02/2018 at 10:15 am, three swabs were observed to be stored on the counter at room temperature waiting to be tested on the Quidel Solana: Patient #725267 and Patient #416757 swabs collection date was 10/01/2018, for Influenza A&B test (BD ESwab Transport System swab) Patient #416757 swab collection date was 10/01/2018, for Strep A test (Puritan Sterile Polyester Tipped Applicator swab) The patient swabs did not include collection times on the swabs, nor did the clinic's system. Only collection dates were solicited. 3. Review of "Progress Notes" and instrument printouts from 07/2018 through 09/2018 for the following patients tested for Influenza A&B did not solicit collection times: Patient #794438 collected 07/31/2018 and analyzed 08/01/2018 at 1:48 pm Patient #460231 collected 07/31/2018 and analyzed 08/01/2018 at 1:48 pm Patient #1104680 collected 07/27/2018 and analyzed 07/28/2018 at 12:12 pm Patient #936551 collected 07/19/2018 and analyzed 07/20/2018 at 4:04 pm Patient #365606 collected 08/02/2018 and analyzed 08/03/2018 at 4:04 pm Patient #460417 collected 08/02/2018 and analyzed 08/03/2018 at 4:04 pm Patient #201347 collected 08/03/2018 and analyzed 08/04/2018 at 11:10 am Patient #530705 collected 08/13/2018 and analyzed 08/14/2018 at 2:51 pm Patient #1150608 collected 08/16/2018 and analyzed 08/17/2018 at 11:06 am Patient #1086572 collected 08/16/2018 and analyzed 08/17/2018 at 11:06 am Patient #1015443 collected 08/21/2018 and analyzed 08/22/2018 at 12:28 pm Patient #539239 collected 08/22/2018 and analyzed 08/23/2018 at 1:15 pm Patient #1021528 collected 09/13/2018 and analyzed 09/14/2018 at 10:54 am Patient #843437 collected 09/19/2018 and analyzed 09/20/2018 at 1:37 pm Patient #813301 collected 09/21/2018 and analyzed 09/22/2018 at 9:54 am Patient #930423 collected 09/24/2018 and analyzed 09/25/2018 at 10:24 am Patient #256032 collected 09/24/2018 and analyzed 09/25/2018 at 12:01 pm Patient #203752 collected 09/25/2018 and analyzed 09/26/2018 at 12:27 pm Note: The laboratory's practice of storing swabs prior to Influenza testing were not according to the manufacturer. Refer to D5311. The laboratory did not ensure collection times were solicited to ensure specimens were tested for all assays within the defined timeframe at the defined storage conditions. 4. During an interview on 10/03/2018 at 12:30 pm, Technical Consultant 1 and 2 confirmed the above findings.

SPECIMEN SUBMISSION, HANDLING, AND REFERRAL

CFR(s): 493.1242(a)

The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

This STANDARD is not met as evidenced by:

Based on direct observation, review of Quidel Solana studies, manufacturer's instructions, laboratory's procedure manual, instrument printouts, progress notes, and in interview with staff, the laboratory failed to ensure patient swabs were stored properly prior to testing for Influenza (A&B) on Quidel Solana for 20 of 20 patients in 2018 (random sampling from 07/2018 through 10/2018). Findings included: 1. Review of Quidel Solana studies for Influenza A&B testing revealed the test method was implemented 07/14/2018. According to Technical Consultant - 2 (TC-2) on 10/02/2018 at 10:35 am, the laboratory stores swabs (for Influenza A&B and strep assay) at room temperature and tests the next day on the Quidel Solana. 2. Review of Quidel manufacturer's instructions for Influenza A&B "SPECIMEN COLLECTION, STORAGE AND HANDLING" stated, "Nasal and nasopharyngeal specimens should be collected, transported, stored, and processed according to CLSI M41-A. Specimens should be stored at 2 to 8 (degrees) C (Celsius) until tested. Specimens collected in BD UTM (1- and 3 - mL), Remel M4 (3-mL), Remel M4RT (3-mL), Remel M5 (3-mL), and Remel M6 (3-mL) are stable at 2 to 8 C for up to 9 days. NOTE: Specimens collected in Copan eSwab transport media are stable at 2 to 8 C for up to 48 hours." The laboratory's procedure manual included the manufacturer's instructions, as their written policy. The manufacturer and the laboratory's policy did not include stability for swabs at room temperature. The laboratory used BD ESwab Transport System collection swabs for Influenza A&B testing. 3. During a tour of the laboratory on 10/02/2018 at 10:15 am, two patient swabs, waiting for Influenza A&B testing, were observed to be stored on the counter at room temperature (Patient #725267 and Patient #416757 collection date was 10/01/2018). The patient swabs did not include collection times. During an interview on 10/02/2018 at 10:55 am, the Regional Trainer was asked whether patient swabs for Influenza A&B testing were stored at room temperature prior to testing the following day, she stated "Yes." During an interview on 10/02/2018 at 11:00 am, Testing Person - 6 (TP-6) was asked whether patient swabs for Influenza A&B were stored at room temperature or refrigerated (2-8C) and in the transport media, he pointed and confirmed the swabs were in the transport media (BD ESwab Transport System) and constantly stored at room temperature in the holder (not in the refrigerator). The laboratory did not ensure patient swabs for Influenza A&B testing were stored at 2 to 8 C prior to testing, as required by the manufacturer. 4. Review of patient "Progress Notes" and instrument printouts with Influenza A&B test results from 07/2018 through 09/2018 revealed the laboratory collected patient specimens (random sampling) and tested on the Quidel Solana the following day (collection time was not documented): Patient #794438 collected 07/31/2018 and analyzed 08/01/2018 at 1:48 pm Patient #460231 collected 07/31/2018 and analyzed 08/01/2018 at 1:48 pm Patient #1104680 collected 07/27/2018 and analyzed 07/28/2018 at 12:12 pm Patient #936551 collected 07/19/2018 and analyzed 07/20/2018 at 4:04 pm Patient #365606 collected 08/02/2018 and analyzed 08/03/2018 at 4:04 pm Patient #460417 collected 08/02/2018 and analyzed

08/03/2018 at 4:04 pm Patient #201347 collected 08/03/2018 and analyzed 08/04/2018 at 11:10 am Patient #530705 collected 08/13/2018 and analyzed 08/14/2018 at 2:51 pm Patient #1150608 collected 08/16/2018 and analyzed 08/17/2018 at 11:06 am Patient #1086572 collected 08/16/2018 and analyzed 08/17/2018 at 11:06 am Patient #1015443 collected 08/21/2018 and analyzed 08/22/2018 at 12:28 pm Patient #539239 collected 08/22/2018 and analyzed 08/23/2018 at 1:15 pm Patient #1021528 collected 09/13/2018 and analyzed 09/14/2018 at 10:54 am Patient #843437 collected 09/19/2018 and analyzed 09/20/2018 at 1:37 pm Patient #813301 collected 09/21/2018 and analyzed 09/22/2018 at 9:54 am Patient #930423 collected 09/24/2018 and analyzed 09/25/2018 at 10:24 am Patient #256032 collected 09/24/2018 and analyzed 09/25/2018 at 12:01 pm Patient #203752 collected 09/25/2018 and analyzed 09/26/2018 at 12:27 pm According to TP - 6 on 10/02/2018 at 10:15 am, the date of collection was based off of the date of service in their system ("Progress Notes"). The laboratory did not ensure patient swabs for Influenza A&B testing were stored in 2-8 degrees Celsius conditions prior to testing the following day, as required by the manufacturer. 5. According to records, the laboratory's total volume for Influenza A&B was 41 tests from 07/2018 through 10/2018. 6. During an exit conference on 10/03/2018 at 12:45 pm, TC-1 and TC-2 reviewed and confirmed the laboratory was not storing patient swabs for Influenza A&B testing in proper conditions prior to testing.

D5393

PREANALYTIC SYSTEMS QUALITY ASSESSMENT
 CFR(s): 493.1249(b)(c)

The preanalytic systems assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of preanalytic systems quality assessment reviews with appropriate staff. The laboratory must document all preanalytic systems quality assessment activities.

This STANDARD is not met as evidenced by:
 Based on direct observation, review of manufacturer's instructions, laboratory's procedure manual, instrument printouts, progress notes, test reports, and Quidel Solana studies, the laboratory's quality assessment (QA) program did not include a review of effectiveness of corrective actions taken to resolve problems and review of procedures to prevent recurrence of problems in preanalytic systems, as evidenced by:
 1. The laboratory failed to ensure time of specimen collection was solicited to ensure specimens were tested on the Quidel Solana (Influenza A&B and Strep A) within the timeframe as defined by the manufacturer for patient testing. Refer to D5305. 2. The laboratory failed to ensure patient swabs were stored properly prior to testing for Influenza (A&B) on Quidel Solana for patients tested. Refer to D5311.

D5411

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

Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

This STANDARD is not met as evidenced by:
 Based on review of Coulter AcT Diff 2 operator's manual, laboratory's procedure

manual, patient data log, patient instrument printouts, troubleshooting protocol documents, final test reports, and confirmed in interview, the laboratory failed to follow manufacturer's instructions for confirmation of parameter codes and flags on patient test results for 3 of 7 patients reviewed in 2018 (random sampling from 07/2018 and 09/2018). Findings included: 1. According to Coulter AcT Diff2 operator's manual section 6.9, page 6-80 the Coulter can create 4 different "Replacement Flags (Codes)" or 5 different "Non-Replacement Flags." The alarms or codes notify the operator about abnormal conditions that can affect the quality of patient test results. Replacement Flags (Codes) are those that replace the parameter results, the flags (codes) indicate the following suggested action according to the manufacturer: +++++ : "For MCV (Red Blood Cell parameter), verify results by alternative method, such as blood film review or spun Hematocrit.": "If for WBC (White Blood Cell) diff parameter, confirm results, do manual differential." Non-Replacement Flags are those that appear next to the parameter results, the flags indicate the following suggested action according to the manufacturer: +: "Overrange result, indicates result is greater than linear range but less than operating range" for measured parameters. "Verify results according to your laboratory's protocol." 1,2,3,4 or M: "Differential parameters failed the internal regional size distributional criteria one specific region (1,2,3,4 or multiple regions). Verify results according to your laboratory's protocol." *: "Possible sample handling problem. Possible dual RBC population. Possible interference with WBC count. Platelet distribution failure. Possible sample interference or instrument problem. See instructions for +++++, +, or ----." 2. Review of the laboratory's "Post Analytical Policies and Procedures" stated, "Interpreting Results: When patient results are flagged with M, 1, 2, 3 repeat the sample after 10-30 minutes. If the repeated sample has no flags, give that result to the physician. If the flags repeat, follow the instructions in Appendix 'A' attached Flag Flow Chart...C. 'X' or '*' next to results data: 1. Check the sample for clots or fibrin strands. If the sample has clots or fibrin re-draw the patient and retest. If not clots or fibrin has been found proceed to step 2. 2. Wait 10-30 minutes, thoroughly mix and rerun the sample. 3. Follow the steps in Flag Flow Chart before reporting patients." 3. Review of patient data log and patient instrument printouts from random sampling of 2018 revealed different Coulter hematology flags. The laboratory did not follow manufacturer's instructions by confirming or verifying flagged results prior to reporting out results to the physician, as follows: 07/06/2018 - Patient #771555 specimen was analyzed at 10:41 am, the flag * appeared next to the White Blood Cell (WBC) result, the analysis was repeated and the flag * remained next to the WBC result (instrument printout). The results were provided to the physician and the specimen was sent to the reference laboratory. 09/20/18 - Patient #121107 specimen was analyzed at 4:03 pm, the flag * appeared next to the Platelet result (instrument printout), the analysis of the specimen was not repeated and results were provided to the physician. The final test report results were consistent with the instrument printout. 09/20/2018 - Patient #1193357 specimen was analyzed at 10:49 am, the flag * appeared next to the White Blood Cell (WBC) result, the analysis was repeated and the flag * remained next to the WBC result (instrument printout). The results were provided to the physician and the specimen was sent to the reference laboratory. 4. During an interview on 10/03/2018 at 12:00 pm, Testing Person - 7 was asked how patient flagged results were handled, she stated, "Flagged results should be repeated. I walk over the results to the doctor, both results are shown (flagged results). The results are then scanned and the specimen is sent to (name of reference laboratory). All results are transmitted into the EMR, even the flagged results. If there is a repeat, those results will override the 1st results." The laboratory did not ensure all flagged results were confirmed or verified prior to reporting patient test results to the physician.

D5415

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

CFR(s): 493.1252(c)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

Based on review of Hematology QC (Quality Control) package insert and confirmed in interview, the laboratory failed to have a system in place to ensure QC was not utilized in excess of 31 times within 35 days according to the package insert. Findings included: 1. Review of the package insert for the Coulter 4C Plus Cell Control stated "35** - Open vial (Days), **Assumes that the instructions for Use section of the package insert is performed a maximum of 31 times within 35 days." 2. During an interview on 10/03/2018 at 10:45 am, Technical Consultant - 1 (TC-1) was asked whether the laboratory had a mechanism in place to track the number of times control material was used (to not exceed 31 times within 35 days), she stated the days QC material were used are counted per lot number and the Testing Person counts the days in the portal. The Testing Person will start a new lot number before the expiration date to stay within the 35 days. During an interview on 10/03/2018 at 10:45 am, TC-1 was asked when an afternoon control level was analyzed was it counted (to not exceed 31 times within 35 days), she stated the afternoon control was not being counted nor was it reported in the portal. The number of times the control material was analyzed per lot number could not be assessed to ensure it was not utilized in excess of 31 times within 35 days.

D5781

CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(1)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's procedure manual, hematology quality control (QC) data, corrective action log, and confirmed in interview, the laboratory failed to document corrective action taken when hematology QC was not within acceptable criteria for 5 of 24 days reviewed in 07/2017. Findings included: 1. Review of the laboratory's "QUALITY CONTROL POLICY" stated, "When one of both levels of QC fails, the first step is to repeat the control which exceeded acceptable limits. If the control is still out of range, check the reagent of the failing analyte for dating and stability. If fresh QC and/or fresh reagents do not bring the QC in range, recalibrate per the manufacturer's instructions. Record the problem and the corrective action." 2.

Review of the Coulter AcT Diff 2 analyzer QC data log from 07/2017 revealed the following days QC was not within acceptable limits and no documented corrective action: 07/11/2017 - QC Normal Level (Lot #075300, expiration date 08/18/18) was outside of limits at 7:40 am, outside limits at 7:43 am, and within limits at 8:22 am. QC High Level (Lot #087100) was outside of limits at 7:44 am, and within limits at 8:24 am. 07/13/2017 - QC Normal Level (Lot #075300, expiration date 08/18/18) was outside of limits at 7:38 am, and within limits at 7:44 am. QC High Level (Lot #087100) was outside of limits at 7:40 am, and within limits at 7:54 am. 07/14/2017 - QC Normal Level (Lot #075300, expiration date 08/18/18) was outside of limits at 7:46 am, outside limits at 8:05 am, and within limits at 8:21 am. QC High Level (Lot #087100) was outside of limits at 8:11 am, and within limits at 8:23 am. 07/20/2017 - QC Low Level (Lot #060100, expiration date 08/18/17) was outside of limits at 7:37 am, and within limits at 7:39 am. QC Normal Level (Lot #075300, expiration date 08/18/17) was outside of limits at 7:41 am, outside limits at 7:43 am, and within limits at 7:46 am. 07/25/2017 - QC Low Level (Lot #060100, expiration date 08/18/17) was outside of limits at 7:38 am, outside of limits at 7:50 am, and within limits at 7:51 am. QC Normal Level (Lot #075300, expiration date 08/18/17) was outside of limits at 7:44 am, and within limits at 7:47 am. Note: Daily QC instrument printouts were not retained for the above days. Refer to D3031. 3. Review of the laboratory's "COULTER ACT DIFF CORRECTIVE ACTION LOG" for 07/2017 revealed the last documented corrective action was 06/29/17. The laboratory failed to document corrective action taken for QC not within acceptable limits in 07/2017. 4. During an interview on 10/03/2018 at 10:30 am, Technical Consultant #1 and #2 reviewed and confirmed the above findings. This is a repeat deficiency from last survey 06/06/2016.

D5793

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(b)(c)

(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's procedure manual, hematology quality control (QC) data, corrective action log, and laboratory's portal, the laboratory's quality assessment (QA) program did not include a review of effectiveness of corrective actions taken to resolve problems and review of procedures to prevent recurrence of problems in analytic systems. Findings included: 1. Review of the laboratory's "QUALITY CONTROL POLICY" stated, "When one of both levels of QC fails, the first step is to repeat the control which exceeded acceptable limits. If the control is still out of range, check the reagent of the failing analyte for dating and stability. If fresh QC and/or fresh reagents do not bring the QC in range, recalibrate per the manufacturer's instructions. Record the problem and the corrective action." Review of the Coulter AcT Diff 2 analyzer QC data log from 07/2017 revealed the 5 of 24 days QC was not within acceptable limits and no documented corrective action. Refer to D5781 (This is a repeat deficiency from last survey 06/06/2016). Note: Daily QC instrument printouts were not retained for the above days. Refer to D3031, III. 2. Review of Coulter AcT Diff 2 daily QC instrument printouts from 07/02/2018 through 10/03/2018 (total of 78 days) revealed there were no QC failures (outside acceptable limits). Review of the laboratory's portal for QC from 07/02/2018 through 10/03/2018

revealed there were no QC failures entered and there was no documented corrective action. Refer to D3031, III. According to Technical Consultant - 1 (TC-1) on 10/03/2018 at 10:30 am, the laboratory's practice was for Testing Persons to document corrective action in the portal (provided by TC-1 consulting company) when QC was outside acceptable limits; and to enter QC levels that are not within acceptable limits into the portal. The laboratory's QC program could not be assessed to determine whether the program was detecting immediate error and that all QC procedures were being documented (QC failures, corrective action). 3. The laboratory's QA program was not effective in review of policies/procedures to prevent recurrence of problems in the laboratory. 4. During an interview on 10/03/2018 at 10:30 am, Technical Consultant #1 and #2 reviewed and confirmed the above 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 direct observation, review of manufacturer's instructions, laboratory's procedure manual, instrument printouts, progress notes, test reports, Quidel Solana studies, hematology quality control (QC) data, and corrective action log, the laboratory director failed to provide overall management and direction, as evidenced by: 1. The laboratory director failed to ensure the preanalytical phase of testing was providing quality laboratory services. Refer to D6007. 2. The laboratory director failed to ensure the quality assessment (QA) program was maintained and identified failures in quality as they occurred. Refer to D6022. 3. The laboratory director failed to ensure all corrective action was taken and documented when test systems performed outside of their acceptable limits. Refer to D6024.

D6007

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(1)

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)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;

This STANDARD is not met as evidenced by:
Based on direct observation, review of manufacturer's instructions, laboratory's procedure manual, instrument printouts, progress notes, test reports, and Quidel Solana studies, the laboratory director failed to ensure the preanalytical phase of testing was providing quality laboratory services, as evidenced by: 1. The laboratory failed to ensure time of specimen collection was solicited to ensure specimens were tested on the Quidel Solana (Influenza A&B and Strep A) within the timeframe as defined by the manufacturer for patient testing. Refer to D5305. 2. The laboratory

failed to ensure patient swabs were stored properly prior to testing for Influenza (A&B) on Quidel Solana for patients tested. Refer to D5311.

D6022

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 and quality assessment programs are established and maintained to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's procedure manual, hematology quality control (QC) data, corrective action log, Quidel Solana studies, manufacturer's instructions, instrument printouts, progress notes, test reports, and laboratory's portal, the laboratory director failed to ensure the quality assessment (QA) program was maintained and identified failures in quality as they occurred, as evidenced by: 1. The laboratory's QA program did not include a review of effectiveness of corrective actions taken to resolve problems and review of procedures to prevent recurrence of problems in preanalytic systems. Refer to D5393. 2. The laboratory's QA program did not include a review of effectiveness of corrective actions taken to resolve problems and review of procedures to prevent recurrence of problems in analytic systems. Refer to D5793.

D6024

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(7)

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)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified,

This STANDARD is not met as evidenced by:

Based on review of the laboratory's procedure manual, hematology quality control (QC) data, and corrective action log, the laboratory director failed to ensure all corrective action was taken and documented when test systems performed outside of their acceptable limits. The laboratory failed to document corrective action taken when hematology QC was not within acceptable criteria for 5 of 24 days reviewed in 07/2017. Refer to D5781.

D6033

TECHNICAL CONSULTANT-MODERATE COMPLEXITY

CFR(s): 493.1409

The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:
Based on direct observation, review of manufacturer's instructions, laboratory's procedure manual, instrument printouts, progress notes, test reports, Quidel Solana studies, hematology quality control (QC) data, and corrective action log, the technical consultant failed to provide technical oversight, as evidenced by: 1. The technical consultant failed to ensure all requirements were met for the preanalytical phase of testing. Refer to D6036. 2. The technical consultant failed to ensure remedial actions were documented whenever the test systems performed outside of their acceptable limits. Refer to D6043.

D6036

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413

The technical consultant is responsible for the technical and scientific oversight of the laboratory.

This STANDARD is not met as evidenced by:
Based on direct observation, review of manufacturer's instructions, laboratory's procedure manual, instrument printouts, progress notes, test reports, and Quidel Solana studies, the technical consultant failed to ensure all requirements were met for the preanalytical phase of testing, as evidenced by: 1. The laboratory failed to ensure time of specimen collection was solicited to ensure specimens were tested on the Quidel Solana (Influenza A&B and Strep A) within the timeframe as defined by the manufacturer for patient testing. Refer to D5305. 2. The laboratory failed to ensure patient swabs were stored properly prior to testing for Influenza (A&B) on Quidel Solana for patients tested. Refer to D5311.

D6043

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(5)

(b) The technical consultant is responsible for-- (b)(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications;

This STANDARD is not met as evidenced by:
Based on review of the laboratory's procedure manual, hematology quality control (QC) data, and corrective action log, the technical consultant failed to ensure remedial actions were documented whenever the test systems performed outside of their acceptable limits. The laboratory failed to document corrective action taken when hematology QC was not within acceptable criteria for 5 of 24 days reviewed in 07 /2017. Refer to D5781.