| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 45D1082475 | 02/21/2018 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| All Childrens Pediatric Clinic Pa | 4221 North Conway Suite D, Palmhurst, 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** | The laboratory was found to be out of compliance based on the following CONDITION LEVEL DEFICIENCIES: D5400 - 42 C.F.R. 493.1250 Condition: Analytic Systems D6000 - 42 C.F.R. 493.1403 Condition: Laboratory Director; moderate complexity Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representative was given an opportunity to provide evidence of compliance with noted deficiencies and no such evidence was provided prior to survey exit. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider /supplier, the State Survey Agency (SA) should be notified immediately. |
| **D5400** | ANALYTIC SYSTEMS<br>CFR(s): 493.1250<br><br>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.<br><br>This CONDITION is not met as evidenced by:<br>Based on review of laboratory policy, review of manufacturer's instructions, review of patient records, review of instrument verification records, and confirmed in interview of facility personnel, the laboratory failed to: 1. The laboratory failed to have a policy to resolve flags on CBC results prior to their release to the healthcare provider. (see D5405) 2. The laboratory failed to perform instrument verification on the Quidel |

| | |
|---|---|
| | Solana analyzer prior to patient testing. (see D5421-A) 3. The laboratory failed to perform new kit validation for Complete Strep testing on the Quidel Solana analyzer. (see D5421-B) 4. The laboratory failed to perform 2 levels of quality control testing on each day of patient testing for the Quidel Solana analyzer. (see D5449) |
| **D5405** | PROCEDURE MANUAL<br>CFR(s): 493.1251(c)<br><br>Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of manufacturer's instructions, random review of final patient reports, and confirmed in interview of facility personnel, the laboratory failed to have a policy to instruct testing personnel on how to resolve flags on CBC (complete blood count) results according to the manufacturer's instructions prior to their release to the healthcare provider. The findings were: 1. Attempted review of laboratory policy on February 21, 2018 at 1230 hours revealed no policy was available for review that would instruct testing personnel on how to resolve flags on CBC results prior to their release to the healthcare provider. 2. Review of the manufacturer's instructions for the Sysmex XP-300 (Code No. AU553517, Revision Date: May 2014) under, "8.3 Histogram flags" stated: Flag: WL Probable sample cause: Incomplete lysing of red blood cells, presence of nucleated red blood cells, increase of large platelets, platelet aggregation or agglutination, precipitation of fibrin, etc. Correction (reference): (1) Centrifuge sample and replace the plasma with equal volume of saline or CELLPACK and repeat analysis. (2) Check smear, etc. Flag: RL Probable sample cause: Presence of fragmented red blood cells, increase of large platelets, platelet aggregation or agglutination, etc. Correction (reference): (1) Manual red blood cell count of sample. (2) Check smear, etc. Flag: PL Probable sample cause: Effects of cryoglobulins, fragmented red blood cells, or cellular fragments of white blood cells, etc. Correction (reference): (1) Warm sample at 37 degrees Celsius for 30 minutes and repeat analysis. (2) Check smear, etc. Flag: WU Probable sample cause: Incomplete lysing of red blood cells, presence of immature white blood cells, white blood cell aggregation, platelet satellite phenomenon, etc. Correction (reference): (1) Centrifuge sample and replace the plasma with equal volume of saline or CELLPACK and repeat analysis. (2) Check smear, etc. Flag: RU Probable sample cause: Effects of cold agglutinin, inclusion of white blood cells, etc. Correction (reference): (1) Warm sample at 37 degrees Celsius for 30 minutes and repeat analysis. (2) Check smear, etc. Flag: PU Probable sample cause: Increase of large platelets, inclusion of fragmented red blood cells, precipitation of cryoglobulins, etc. Correction (reference): (1) Manual platelet count of sample. (2) Check smear, etc. Flag: DW (RBC) Probable sample cause: Significant anisocytosis, etc. Correction (reference): (1) Check smear, etc. Flag: DW (PLT) Probable sample cause: Inclusion of fragmented red blood cells, non-uniformity in size of platelets, effects of cryoglobulins. Correction (reference): (1) Check smear, etc. (2) Centrifuge sample and replace plasma with equal volume of saline or CELLPACK and repeat analysis, warm sample at 37 degrees Celsius for 30 minutes and repeat analysis, etc." Flag: MP (RBC) Probable sample cause: Effects of anemia treatment or blood transfusion causing the presence of cells of multiple sizes. Correction (reference): (1) Check smear, etc. Flag: MP (PLT) Probable sample cause: Platelet aggregation, sample with low values for platelets. Correction (reference): |

| | |
|---|---|
| | Check smear, etc. Flag: T1 Probable sample cause: Presence of CML or other immature granulocytes, incomplete lysing of red blood cells, etc. Correction (reference): (1) Check smear, etc. (2) Centrifuge sample and replace the plasma with equal volume of saline or CELLPACK and repeat analysis, warm sample at 37 degrees Celsius for 30 minutes and repeat analysis, etc. Flag: T2 Probable sample cause: Presence of CML or other immature granulocytes, incomplete lysing of red blood cells, aged sample, etc. Correction (reference): (1) Check smear, etc. (2) Centrifuge sample and replace the plasma with equal volume of saline or CELLPACK and repeat analysis, warm sample at 37 degrees Celsius for 30 minutes and repeat analysis, etc. Flag: F1, F2, F3 Probable sample cause: Presence of CMS or other immature granulocytes, incomplete lysing of red blood cells, aged sample, etc. Correction (reference): (1) Check smear, etc. (2) Centrifuge sample and replace the plasma with equal volume of saline or CELLPACK and repeat analysis, warm sample at 37 degrees Celsius for 30 minutes and repeat analysis, etc. Flag: AG Probable sample cause: Presence of nucleated red blood cells, effects of fragmented red blood cells, increase of large platelets, platelet aggregation or agglutination, precipitation of fibrin, etc. Correction (reference): Check smear, etc. 3. Random review of final patient reports from December 2017 revealed the following patient results that were released to the healthcare provider with flags (see patient alias list): Patient 1 Date Resulted: 12/01/2017 Flag: AG Patient 2 Date Resulted: 12/01/2017 Flag: AG Patient 3 Date Resulted: 12/12/2017 Flag: AG* Patient 4 Date Resulted: 12/12/2017 Flag: AG Patient 5 Date Resulted: 12/12/2017 Flag: AG Patient 6 Date Resulted: 12/07 /2017 Flag: T2, AG Patient 7 Date Resulted: 12/01/2017 Flag: AG Patient 8 Date Resulted: 12/12/2017 Flag: T2, AG Patient 9 Date Resulted: 12/01/2017 Flag: WL, AG Patient 10 Date Resulted: 12/11/2017 Flag: F2, F3, AG Patient 11 Date Resulted: 12/01/2017 Flag: WL, AG Patient 12 Date Resulted: 12/20/2017 Flag: WL, AG Patient 13 Date Resulted: 12/12/2017 Flag: AG Patient 14 Date Resulted: 12/09/2017 Flag: AG Patient 15 Date Resulted: 12/12/2017 Flag: AG Patient 16 Date Resulted: 12 /11/2017 Flag: AG Patient 17 Date Resulted: 12/09/2017 Flag: AG Patient 18 Date Resulted: 12/01/2017 Flag: AG Patient 19 Date Resulted: 12/09/2017 Flag: AG Patient 20 Date Resulted: 12/20/2017 Flag: WL, AG Patient 21 Date Resulted: 12/07 /2017 Flag: AG Patient 22 Date Resulted: 12/05/2017 Flag: AG Patient 23 Date Resulted: 12/05/2017 Flag: AG Patient 24 Date Resulted: 12/05/2017 Flag: AG Patient 25 Date Resulted: 12/06/2017 Flag: AG Patient 26 Date Resulted: 12/06/2017 Flag: AG Patient 27 Date Resulted: 12/06/2017 Flag: AG Patient 28 Date Resulted: 12 /06/2017 Flag: AG Patient 29 Date Resulted: 12/20/2017 Flag: AG Patient 30 Date Resulted: 12/20/2017 Flag: AG 4. The laboratory was asked to provide documentation of resolving the flags according to the manufacturer's instructions. No documentation was provided. 5. An interview with the technical consultant on 02/21/2018 at 1257 hours in the store room confirmed the findings. Key: CML - Chronic Myeloid Leukemia |
| **D5421** | ESTABLISHMENT AND VERIFICATION OF PERFORMANCE<br>CFR(s): 493.1253(b)(1)<br><br>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. |

| | |
|---|---|
| | This STANDARD is not met as evidenced by:<br>A. Based on direct observation, review of the laboratory's verification records for the Quidel Solana and staff interview, it was revealed the laboratory failed to ensure verification studies were complete prior to performing patient testing. The findings were: 1. Direct observation made by the surveyor on 02/21/2018 at 1400 hours in the laboratory revealed the serial number for the Quidel Solana currently in use was 16020334. 2. The laboratory was asked to provide documentation of the verification studies performed on the analyzer. The verification studies provided for review were for a Quidel Solana, serial number 1502066. 3. An interview with the technical consultant and testing personnel 1 (as listed on CMS Form 209) on 02/21/2018 at 1415 hours in the store room confirmed the findings. Testing person 1 confirmed the laboratory had received a new analyzer around October or November 2017 due to "invalid" issues with the previous analyzer. B. Based on direct observation, review of instrument verification studies, review of patient records, and confirmed in interview of facility personnel, the laboratory failed to validate the Quidel Complete Strep kit currently in use by the laboratory. The findings were: 1. Direct observation made by the surveyor on 02/21/2018 at 1430 hours in the laboratory revealed the laboratory utilized the Solana Strep Complete ASSAY for streptococcus testing on the Quidel Solana analyzer. When testing personnel number 1 as listed on Form CMS-209 was asked if this was the current kit type used by the laboratory, she stated, "Yes." Current Lot #: 112723 Expiration Date: 11/06/2018 2. Review of patient test runs from July 2017 to February 2018 revealed the laboratory began testing with the Solana Strep Complete ASSAY on October 14, 2017. 3. The laboratory was asked to provide documentation of the verification studies performed on the test kit prior to patient testing. No documentation was provided. 4. As documented on the Form CMS-116, signed by the laboratory director on 02/21/2018, the laboratory performed 1200 patient tests annually. 5. The findings were confirmed in interview of testing personnel 1 and the technical consultant on02/21/2018 at 1500 hours in the store room. |
| **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 review of manufacturer's instructions, review of quality control records from July 2017 to February 2018, review of patient final reports, and confirmed in interview of facility personnel, the laboratory failed to perform 2 levels of quality control each day of patient testing on the Quidel Solana for Streptococcus testing. The findings were: 1. Review of the manufacturer's instructions for Solana Strep Complete Assay (PIM301004EN00 8/17) under, "Quality Control" stated, "It is recommended that the reactivity of each new lot and each new shipment of the Solana Strep Complete Assay be verified on receipt and before use. External control tests should be performed thereafter in accordance with appropriate federal, state and local guidelines. The Solana Strep Complete Assay should not be used in patient testing if the external controls do not produce correct results." 2. The manufacturer's |

| | |
|---|---|
| | instructions are less stringent than the CLIA regulations. The laboratory is required to performed at least 2 levels of quality control testing each day of patient testing. 3. The laboratory did not develop an IQCP for qualitative testing on the Quidel Solana. The laboratory is required to perform at least 2 levels of quality control each day of patient testing. 4. Review of patient results from January 2017 to February 2018 revealed the following patient results were tested when quality control testing was incomplete or not performed: July 12, 2017 Unique IDs: 15020266013807 15020266013808 15020266013809 15020266013810 15020266013811 15020266013812 15020266013901 15020266013912 15020266013902 15020266013903 15020266013904 15020266013905 15020266013906 15020266013907 15020266013908 15020266013909 15020266013910 15020266013911 15020266014001 15020266014002 15020266014003 15020266014004 15020266014005 15020266014006 15020266014007 15020266014009 15020266014011 15020266014008 15020266014010 15020266014012 15020266013703 15020266013705 15020266013707 15020266013709 15020266013704 15020266013706 15020266013708 15020266013710 15020266013711 15020266013801 15020266013803 15020266013805 15020266013712 15020266013802 15020266013804 15020266013806 February 15, 2018 15020266042503 15020266042504 15020266042505 15020266042506 15020266043402 15020266043403 15020266043404 15020266043405 15020266043406 15020266043501 15020266043502 15020266043503 15020266043203 15020266043204 15020266043205 15020266043206 15020266043202 15020266042801 15020266042802 15020266042803 15020266042804 15020266042806 15020266042805 15020266042901 15020266042903 15020266042906 15020266042902 15020266042905 15020266042904 15020266043002 15020266043003 15020266043004 15020266043005 15020266043006 15020266043001 15020266043104 15020266043506 15020266043505 15020266043504 15020266043105 15020266043101 15020266043102 15020266043103 15020266024801 15020266025001 15020266022802 15020266024805 15020266042601 15020266042602 5. The laboratory was asked to provide documentation of performing at least 2 levels of quality control testing each day of patient testing. No documentation was provided. 6. The above findings were confirmed in interview with the technical consultant on 02/21/2018 at 1446 hours in the store room. |
| **D5793** | ANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1289(b)(c)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>Review of laboratory policy, review of manufacturer's instructions, review of quality control records, review patient results and confirmed in interview of facility personnel revealed the laboratory's quality assurance policy failed to identify problems in analytic systems a evidenced by: 1. The laboratory's quality assurance program failed to identify that flags on CBC (complete blood count) results were not resolved prior to their release to the healthcare provider. (refer to D5405) 2. The laboratory's quality assurance program failed to identify that complete verification studies on the Quidel |

| | |
|---|---|
| | Solana analyzer were performed prior to patient testing in November 2017. (refer to D5421-A) 3. The laboratory's quality assurance program failed to identify that complete verification studies were complete when it switched kits to the Quidel Solana Complete Strep kit from the GAS (Group A Strep) kit in November 2017. (refer to D5421-B) 4. The laboratory's quality assurance program failed to identify that quality control testing was not performed each day of patient testing from July 2017 to February 2018. (refer to D5449) |
| **D6000** | MODERATE COMPLEXITY LABORATORY DIRECTOR<br>CFR(s): 493.1403<br><br>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.<br><br>This CONDITION is not met as evidenced by:<br>Based on direct observations, review of manufacturer's instructions, review of new analyzer verification records, review of quality control records, review of patient results, and confirmed in interview of facility personnel, the laboratory director failed to provide overall management and direction of the laboratory. (refer to D6013, D6020, D6021, D6031) |
| **D6013** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(3)(ii)<br><br>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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;<br><br>This STANDARD is not met as evidenced by:<br>Based on direct observations, review of new analyzer verification records, and confirmed in interview of facility personnel, the laboratory director failed to ensure verification studies were performed on the QUIDEL Solana analyzer prior to patient testing. (refer to D5421) |
| **D6020** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(5)<br><br>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.<br><br>This STANDARD is not met as evidenced by: |

| | |
|---|---|
| | Based on review of manufacturer's instructions, review of quality control records from July 2017 to February 2018, review of patient results, the laboratory director failed to ensure two levels of quality control testing were performed on each day of patient testing. (refer to D5449) |
| **D6021** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(5)<br><br>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory policy, review of quality control records, review of patient results, and confirmed in interview of facility personnel, the laboratory director failed to ensure the laboratory quality assurance program identified errors in analytic systems. (refer to D5793) |
| **D6031** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(13)<br><br>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory policy, review of manufacturer's instructions, review of patient final reports, and confirmed in interview of facility personnel, the laboratory director failed to ensure a policy was available to testing personnel on how to resolve flags on CBC (complete blood count) results prior to their release to the healthcare provider. (refer to D5405) |