| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 45D0994691 | 01/23/2018 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| All Children's Pediatric Clinic P A | 6900 N 10th Ste 8, Mcallen, 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 |
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| **D0000** | Noted deficiencies and plans of correction were discussed with the laboratory representative at the entrance and exit conferences. The facility representative was 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. 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. |
| **D1001** | CERTIFICATE OF WAIVER TESTS<br>CFR(s): 493.15(e)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the manufacturer's instructions for the KENLOR Liquid H. Pylori Human IgG Antibody Serum Control, surveyor observation of control material currently in use in the laboratory, review of the laboratory's quality control records from 2015, 2016 and 2017, and staff interview, it was revealed the laboratory failed to have documentation of following the manufacturer's instructions for control stability. The findings were: 1. A review of the manufacturer's instructions for the KENLOR Liquid H. Pylori Human IgG Antiobody Serum Control (150303-014525) under the section titled "Storage and Stability" revealed: "Once opened it is stable for 60 days." 2. Surveyor observation of control material currently in use by the laboratory on 01/23 |

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| | /2018 at 1010 hours in Lab Station #1 revealed laboratory had a single box of KENLOR controls consisting on a single vial of each of the two levels of control material (level 1: Lot 014521 and level 2: Lot 014522). The outside of the box was documented with being opened on 08/03/2015. 3. A review of the laboratory's quality control records from 2015, 2016, and 2017 revealed the laboratory opened and used this control on 08/03/2015. Thus, following the manufacturer's instructions, the controls expired on 10/02/2015. 4. Further review of the laboratory's quality control records revealed the expired controls were used for quality control testing on the following days: 11/21/2015 01/20/2016 03/22/2016 04/21/2016 06/13/2016 08/02 /2016 08/31/2016 09/21/2016 12/12/2016 01/12/2017 01/29/2017 02/13/2017 02/28 /2017 05/04/2017 12/15/2017 5. The laboratory reported performing H. Pylori testing on 184 patient samples in 2016 and 138 patients in 2017. 6. An interview with the technical consultant on 01/23/2018 at 1015 hours in Lab Station #1 - after her review of the records- confirmed the findings. |
| **D2007** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(1)<br><br>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<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's American Proficiency Institute's proficiency testing records from 2016 and 2017, and staff interview, it was revealed the laboratory failed to have documentation of rotating proficiency testing among personnel who routinely performed patient testing. The findings were: 1. A review of the laboratory's submitted Form CMS 209 (approved by the laboratory director on 01/19/2017) revealed the laboratory identified 8 testing personnel who routinely performed hematology testing. 2. A review of the laboratory's American Proficiency Institute's proficiency testing records from 2016 (Hematology events 1, 2, and 3) and 2017 (Hematology events 1, 2, and 3) revealed the laboratory failed to have documentation of 4 of 8 testing personnel testing proficiency samples. The personnel who did not participate in proficiency testing were (as listed on Form CMS 209): Testing personnel number 3 Testing personnel number 5 Testing personnel number 7 Testing personnel number 9 3. An interview with the technical consultant on 01/23/2018 at 1000 hours in Lab Station #2 - after her review of the records - confirmed the findings. |
| **D5401** | PROCEDURE MANUAL<br>CFR(s): 493.1251(a)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's policies, review of patient test records from December 2017, and staff interview, it was revealed the laboratory failed to have |

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| | documentation of following its policy for repeating CBC (complete blood count) results. The findings were: 1. A review of the laboratory's policy titled "Policy for Repeating CBC Tests" (approved by the laboratory director on 09/01/2014) revealed: "In an effort to ensure accuracy in patient CBC testing, it is the policy of this laboratory to repeat tests when patient results are outside the following range: RBC less than 3.50 or greater than 7.00 million WBC less than 2.50 or greater than 22.0 thousand HCT less than 27% or greater than 48% HGB less than 9 or greater then 16 mg/% PLT less than 100 or greater than 450 thousand 2. A review of patient CBC results from December 2017 identified the following patients whose results met the laboratory's criteria for repeating: Date ID Test(s) 12/03 11-21-11 WBC: 26.0 12/04 02-21-2004 HGB: 16.1 HCT: 50.0 12/04 8-11-17 HGB: 17.0 HCT: 50.9 12/04 1-6-14 WBC: 23.0 PLT: 475 12/11 3-28-17 PLT: 494 12/12 6-9-17 PLT: 461 12/13 6-18-13 WBC: 25.9 12/23 10-9-98 HCT: 48.1 3. The laboratory was asked to provide documentation of repeating the identified tests following its policy. No documentation was provided. 4. An interview with the technical consultant on 01/23/2018 at 1110 hours in Lab Station #2 - after her review of the records- confirmed the findings. Key WBC: white blood cell RBC: red blood cell HCT: hematocrit HGB: hemoglobin PLT: platelet |
| **D5411** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(a)<br><br>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.<br><br>This STANDARD is not met as evidenced by: |
| **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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's verification studies performed on the Sysmex XP-300 hematology analyzer, review of the laboratory's verification studies performed on the Quidel Solana analyzer #2, and staff interview, it was revealed the laboratory failed to have documentation of complete verification studies. The findings were: 1. A review of the laboratory's verification studies performed on the Sysmex XP-300 hematology analyzer in February 2016 revealed the laboratory failed to have documentation of evaluating patient correlation test results to assess the accuracy of the test system. The laboratory tested 5 samples and then sent the same samples to another laboratory to be tested. The results from the second laboratory were never returned to the laboratory so accuracy could be assessed. 2. A review of the |

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| | laboratory's verification studies performed on the Quidel Solana analyzer #2 in November 2017 revealed the laboratory failed to have documentation of assessing the precision of the test system. 3. The laboratory was asked to provide documentation of the missing studies. No documentation was provided. 4. Interviews with the technical consultant on 01/23/2018 at 1035 and on 01/23/2018 at 1300 hours in Lab Station #2 - after her review of the records- confirmed the findings. |
| **D5429** | MAINTENANCE AND FUNCTION CHECKS<br>CFR(s): 493.1254(a)(1)<br><br>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's maintenance records for the Sysmex XP-300 hematology analyzer from July 2017 to December 2017, and staff interview, it was revealed the laboratory failed to have documentation of performing weekly maintenance as required. The findings were: 1. A review of the laboratory's maintenance records for the Sysmex XP-300 hematology analyzer from July 2017 to December 2017 revealed the following maintenance was to be performed weekly: Clean SRV tray 2. Further review of the laboratory's maintenance records revealed the laboratory failed to have documentation of performing weekly maintenance at the following times: a) July 2017 (1 of 5 weeks missing) week of July 22, 2017 b) September 2017 (1 of 5 weeks missing) week of September 9, 2017 c) October 2017 (1 of 5 weeks missing) week of October 8, 2017 d) November 2017 (1 of 4 weeks missing) week of November 12, 2017 e) December 2017 (1 of 5 weeks missing) week of December 24, 2017 3. The laboratory was asked to provide documentation of performing the maintenance as required. No documentation was provided. 4. An interview with the technical consultant on 01/23/2018 at 1220 hours in Lab Station #2 - after her review of the records- confirmed the findings. |
| **D5445** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(1)(2)(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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's IQCP studies, and staff interview, it was revealed the laboratory failed to have documentation of performing quality control testing to support its modified quality control testing. The findings were: 1. A review of the laboratory's IQCP studies for the Quidel Solana analyzer #1 (approved 02/02/2016) and Quidel Solana analyzer #2 (approved 11/22/2017) revealed the laboratory's modified frequency of quality control testing was: - with each shipment - with each |

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| | new lot - monthly 2. Further review of the laboratory's IQCP studies revealed the laboratory's evidence to support the frequency modification of the control was: a) analyzer #1 Controls were tested twice (on 01/20/16 and 02/03/2016) b) analyzer #2 Controls were testing once (on 11/22/2017) 3. The laboratory was asked to provide documentation of performing quality control testing each day for at least the length of the modifications. No documentation was provided. 4. An interview with the technical consultant on 01/23/2018 - after her review of the records- confirmed the findings. |
| **D5781** | CORRECTIVE ACTIONS<br>CFR(s): 493.1282(b)(1)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the manufacturer's instructions for the Sysmex XP-300 hematology analyzer, review of patient CBC results from December 2017, and staff interview, it was revealed the laboratory failed to have documentation of performing corrective actions to resolve flags on CBC (complete blood count) results. The findings were: 1. A review of the manufacturer's instructions for the Sysmex XP-300 hematology analyzer (Code No.AU553517, May 2014) under the section titled "Analysis of histogram" revealed: "Analysis of histogram allows use of the flagging system that suggests sample error or instrument error." 2. Further review of the manufacturer's instructions revealed the following flags were listed by the manufacturer: a) WL - Relative frequency for Lower discriminator (LD) exceeds the range. Probable cause is inclusion of numerous platelet agglutinations, large platelets, and etc. b) F1 - Small cell histogram error. Relative frequency for T1 exceeds the range. c) F2 - Middle cell histogram error. Relative frequency for T1 or T2 exceeds the range. d) AG - The particle count equal to or less than the LD exceeds a prescribed range. Probable cause is platelet agglutination, which does not alter WBC count but may result in decreased platelet count. 3. A review of patient test records from December 2017 identified the following CBC reports with flagged results which were reported to the providers: Date ID Flag(s) 12/01 01-133-2015 AG 12/01 6-22-01 AG 12/02 8-22-16 AG 12/02 12-18-2015 AG 12/03 9-9-11 AG 12/03 6-16-15 AG 12/03 11-21-11 AG 12/03 3-14-10 AG 12/03 1-9-01 AG 12/03 2-28-6 AG 12/04 4-8-15 AG 12/04 8-31-04 AG 12/04 05-26-2014 AG 12/04 10-19-13 AG 12/04 11-21-11 AG 12 /04 2-17-16 AG 12/04 7-12-06 AG 12/04 3-1-17 AG 12/04 1-5-08 AG 12/04 2-5-17 AG 12/04 02-23-2012 AG 12/04 11-15-11 AG 12/04 02-21-2004 AG 12/04 12-29-04 AG 12/04 8-11-17 AG 12/04 1-6-14 AG 12/05 12-16-03 AG 12/05 7-01-04 AG 12/05 10-9-10 AG 12/05 03-30-07 AG 12/05 10-23-10 AG 12/05 ERICK AG 12/05 07-25-07 AG 12/06 07-13-2016 AG 12/06 10-11-02 AG 12/06 09-07-2013 AG 12/06 04-02-2007 AG 12/06 12-27-2012 AG 12/07 06-14-2010 AG 12/07 2-5-17 AG 12/07 1-30-8 AG 12/07 5-11-12 AG 12/07 3-8-9 AG 12/08 9-13-01 AG 12/08 11-5-12 AG 12/08 10-1-00 AG 12/09 5-26-15 AG 12/09 4-16-04 AG 12/09 1-25-11 AG 12/09 12-23-12 AG 12/10 11-3-15 AG 12/10 66-13 AG 12/10 4-6-17 AG 12/10 7-9-15 AG 12/10 11- |

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| | 23-5 AG 12/10 1-18-8 AG 12/10 01-24-2015 AG 12/10 11-5-12 AG 12/11 3-28-17 AG 12/11 7-12-07 AG 12/11 5-24-17 AG 12/11 BRIANA AG 12/11 MRS 956 AG 12 /11 SAMANTHA AG 12/11 5-23-08 AG 12/12 DEVEN AG 12/12 6-9-17 AG 12/12 8-16-14 AG 12/12 5-22-1 AG 12/12 10-9-14 AG 12/12 10-9-14 AG 12/12 2-18-13 AG 12/12 2-22-11 AG 12/13 6-18-13 AG 12/13 04-11-17 F1, F2 12/13 1-31-03 AG 12 /14 06-18-2013 AG 12/14 8-2-4 AG 12/14 4-22-8 AG 12/14 10-5-14 AG 12/14 JATHAN AG 12/14 8-23-11 AG 12/15 1-3-16 AG 12/15 11-6-15 AG 12/15 8-17-11 AG 12/15 7-15-10 AG 12/15 4-20-09 AG 12/16 2-20-15 AG 12/16 9-11-17 AG 12/16 7-16-12 AG 12/17 05-18-2006 AG 12/17 10-24-2007 AG 12/17 1-13-2 AG 12/17 5-15-4 AG 12/17 9-9-00 AG 12/18 ALEJANDRO AG 12/18 1-5-15 AG 12/18 7-16-12 AG 12/18 8-25-10 AG 12/18 03-11-08 AG 12/18 12-14-99 AG 12/18 03-31-03 AG 12 /18 5-16-04 WL, AG 12/18 10-18-09 AG 12/18 04-7-99 AG 12/19 10-31-03 AG 12 /19 11-10-2008 AG 12/19 10-5-15 AG 12/19 04-07-08 AG 12/19 4-21-17 AG 12/19 02-11-2013 AG 12/20 10-11-2015 AG 12/20 01-11-2011 AG 12/20 06-18-2009 AG 12/20 11-24-5 AG 12/21 7-26-06 AG 12/21 9-21-17 AG 12/21 7-23-15 AG 12/21 04-22-15 AG 12/22 11-06-13 AG 12/22 07-13-2009 AG 12/22 03-02-2015 AG 12/22 DEMETRIUS AG 12/23 4-25-17 AG 12/23 4-1-15 AG 12/23 10-9-98 AG 12/23 1-29-15 AG 12/23 11-25-5 AG 12/23 1-29-09 AG 12/23 11-15-11 AG 12/24 6-1-16 AG 12 /26 8-27-06 WL, AG 12/26 6-17-05 AG 12/26 10-01-2014 AG 12/26 9-23-10 AG 12 /26 6-10-2014 AG 12/26 5-13-13 AG 12/27 1-20-01 AG 12/27 6-25-08 AG 12/28 6-25-08 AG 12/28 5-24-02 AG 12/29 6-25-08 AG 12/29 12-23-08 AG 12/29 9-27-07 AG 12/29 7-8-15 AG 12/30 02-17-2016 AG 4. The laboratory was asked to provide documentation of performing corrective actions to ensure accurate test results were reported. No documentation was provided. 5. An interview with the technical consultant on 01/23/2018 at 1110 hours in Lab Station #2 - after her review of the records- confirmed the findings. |
| **D5785** | CORRECTIVE ACTIONS<br>CFR(s): 493.1282(b)(3)<br><br>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's environmental monitoring records, and staff interview, it was revealed the laboratory failed to have documentation of performing corrective actions when the documented refrigerator or room humidity levels were outside the laboratory's acceptable temperature ranges. The findings were: 1. A review of the laboratory's environmental monitoring records from January 2017 and September 2017 revealed the laboratory's defined acceptable ranges were: a) refrigerator 36 - 46F b) humidity 30 - 85% 2. Further review of the records revealed the following days where the documented value was outside the laboratory's acceptable ranges: a) January 2017 Date 01/08 humidity 26% 01/23 humidity 27% 01 /31 humidity 29% b) September 2017 Date 09/30 refrigerator 35F 3. The laboratory was asked to provide documentation of performing corrective actions as required. No documentation was provided. 4. An interview with the technical consultant on 01/23 /2018 at 1225 hours in Lab Station #2 - after her review of the records- confirmed the findings. |
| **D5813** | TEST REPORT<br>CFR(s): 493.1291(g) |

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| | The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's policies, review of patient test records from December 2017, and staff interview, it was revealed the laboratory failed to have documentation of the notification of critical values. The findings were: 1. A review of the laboratory's policy titled "Critical Values" (approved by the laboratory director on 09/01/2014) revealed: "The Laboratory Personnel will immediately notify the requester or user about lab results in the 'Critical Value' or Panic Range". The policy defined the laboratory's critical values as: WBC less than 2 or greater than 20 HGB less than 7.5 or greater than 18 HCT less than 25 or greater than 55 PLT less than 50 or greater than 800 2. A review of the laboratory's policy titled "Reporting Critical Values" (approved by the laboratory director on 09/01/2014) revealed: "It is the policy of this laboratory to document the reporting of Critical Values. Document - Who was notified - When was the person notified - By whom was the person notified 3. A review of patient test records from December 2017 revealed the following patient results which met the laboratory's criteria as a critical value: Date ID Test 12/02 12-18-2015 WBC: 24.9 12/03 11-21-11 WBC: 26.0 12/04 1-6-14 WBC: 23.0 12/13 6-18-13 WBC: 25.9 12/22 DEMETRIUS WBC: 24.7 4. The laboratory was asked to provide documentation of notify the provider of the identified critical values as stated in its policy. No documentation was provided. 5. An interview with the technical consultant on 01/23/2018 at 1115 hours in Lab Station #1 - after his review of the records-confirmed the findings. |
| **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 review of the laboratory's verification records, and staff interview, it was revealed the laboratory director failed to ensure verification studies were complete (refer to D5421). |