

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2072399	(X3) Date Survey Completed 04/08/2022
Name of Provider or Supplier 1st Choice Pediatrics	Street Address, City, State 1205 North 6th Street, Longview, 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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. .
D2009	Based on the review of the API proficiency testing records from 2020-2021, and confirmed in an interview found the laboratory failed to ensure the TP and/or LD documented attestation sheets to the routine integration of the samples into the patient workload using the laboratory's routine methods for five of six PT testing events. The findings were: 1. Review of the API proficiency testing records from 2020-2021 revealed no documentation of the TP and/or LD attestation for five of six test events. 2020 Hematology/Coagulation-1st event 2020 Hematology/Coagulation-2nd event 2021 Hematology/Coagulation-1st event 2021 Hematology/Coagulation-2nd event 2021 Hematology/Coagulation-3rd event 2. An interview with the manager on 4/7/22 at 10:15 am in the office confirmed the above findings. Key: API= American Proficiency Institute TP=Testing personnel LD=Laboratory director PT=Proficiency testing
D2121	Based on the review of the laboratory's API proficiency test results from 2020-2021 and confirmed in an interview found the laboratory failed to attain a score of at least 80 percent for six of six regulated analytes in 2020 Hematology/Coagulation-1st event. The findings were: 1. Review of the laboratory's API proficiency test results from 2020-2021 revealed the laboratory received scores of less than 80% for six of six regulated analytes in 2020 Hematology/Coagulation-1st event. Regulated Analyte Score (%) Erythrocyte Count 40% Hematocrit 40% Hemoglobin 40% Leukocyte Count 40% Platelets 20% White Blood Cell Differential 60% 2. Further review of the API proficiency test results for the 2020 Hematology/Coagulation-1st event revealed the following proficiency samples received unacceptable performance for the above analytes. Erythrocyte Count (x 10E9/L) HSY-01 Reported Result: 4.32 Expected Results: 4.89-5.53 HSY-02 Reported Result: 2.34 Expected Results: 4.04-4.56 HSY-03 Reported Result: 6.21 Expected Results: 2.26-2.56 Hematocrit (%) HSY-01

Reported Result: 36 Expected Results: 41-47 HSY-02 Reported Result: 18 Expected Results: 32-37 HSY-03 Reported Result: 54 Expected Results: 16-19 Hemoglobin (g/dL) HSY-01 Reported Result: 12.4 Expected Results: 14.7-17.1 HSY-02 Reported Result: 6.1 Expected Results: 11.4-13.2 HSY-03 Reported Result: 19.1 Expected Results: 5.6-6.5 Leukocyte Count (x 10E9/L) HSY-01 Reported Result: 7.8 Expected Results: 15.1-20.6 HSY-02 Reported Result: 3.6 Expected Results: 6.0-8.3 HSY-04 Reported Result: 17.6 Expected Results: 10.6-14.3 Platelets (x 10E9/L) HSY-01 Reported Result: 226 Expected Results: 385-644 HSY-02 Reported Result: 53 Expected Results: 163-274 HSY-03 Reported Result: 119 Expected Results: 40-68 HSY-04 Reported Result: 483 Expected Results: 91-152 White Blood Cell Differential Lymphocytes (%) HSY-02 Reported Result: 25.6 Expected Results: 27.0-31.9 HSY-03 Reported Result: 38.3 Expected Results: 19.8-26.4 Neut/Gran (%) HSY-01 Reported Result: 57.0 Expected Results: 47.7-53.2 HSY-02 Reported Result: 64.0 Expected Results: 55.7-62.1 HSY-03 Reported Result: 48.1 Expected Results: 62.6-70.6 3. An interview with the manager on 4/7/22 at 10:40 am in the office confirmed the above findings. Key: API=American Proficiency Institute

D2122

Based on the review of the CASPER Report 155 report, the review of the laboratory's API proficiency test results from 2020-2021 and confirmed in an interview found the laboratory failed to attain an overall acceptable score of at least 80 percent for six of six regulated analytes in 2020 Hematology/Coagulation-1st event. The findings were: 1. Review of the CASPER 155 report revealed the laboratory attained an overall unacceptable score of 40% in Hematology in 2020 Hematology/Coagulation-1st event. 2020 Hematology/Coagulation-1st event 40% 2. Review of the laboratory's API proficiency test results from 2020-2021 revealed the laboratory received scores of less than 80% for six of six regulated analytes in 2020 Hematology/Coagulation-1st event. Regulated Analyte Score (%) Erythrocyte Count 40% Hematocrit 40% Hemoglobin 40% Leukocyte Count 40% Platelets 20% White Blood Cell Differential 60% 3. An interview with the manager on 4/7/22 at 10:40 am in the office confirmed the above findings. Key: CASPER=Certification and Survey Provider Enhanced Reporting API=American Proficiency Institute

D3000

Based on the surveyor's direct observation, IFU from FDA website, the review of the laboratory's COVID testing records from 2020-2022, and confirmed in an interview found the laboratory failed to report 71 positive Rapid SARS-CoV-2 Antigen test results as required by 42 CFR 493.41 and 493.1100(a) for 15 of 15 months reviewed from 12/2/2020 to 2/11/2022. The findings were: 1. Review BD Veritor system for Rapid Detection of SARS-CoV-2 with the BD Veritor Plus Analyzer IFU (REF: 256082; 2021-03; L012304(05)) under Conditions of Authorization for the Laboratory revealed "Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate." 2. Review Quidel Sofia2 Flu+SARS Antigen IFU (RED: 20390) under Conditions of Authorization for the Laboratory and Patient Care Settings revealed "Authorized laboratories using your product will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate." 3. Review of the laboratory COVID testing log from December 2020 to May 2021 revealed the laboratory used BD Veritor rapid COVID device (SN#: 2010160JC9620) from December 2020 to May 2021. 4. Surveyor's direct observation revealed the laboratory performs rapid Flu+SARS antigen on two of two Quidel Sofia2 devices (SN#: 25020437 and SN#: 25004550) starting from January 2021 to current. 5. Review of the COVID testing records from 12/2/2020 to 2/11/2022 provided by the facility revealed 438 patients were tested for SARS-CoV-2. Refer to Patient alias List for 45D2072399 for Rapid COVID testing. 6. An interview with the

	<p>manager on 4/7/2022 at 9:30 am in the office confirmed the above findings. The manager stated the facility reported to a local health authority in the beginning of pandemic via phone and the facility stopped reporting thinking it was not necessary. Key: IFU=Instruction for Use FDA=Food and Drug Administration</p>
<p>D3031</p>	<p>Based on review of the laboratory's CBC QC records from 2020-2021 and confirmed in an interview found that the laboratory failed to retain 22 of 24 QC lots of Sysmex EIGHTCHECK-3WP X-TRA hematology control assay sheets for a minimum of 2 years. The findings were: 1. Review of the laboratory Sysmex EIGHTCHECK-3WP X-TRA hematology control assay sheets revealed the laboratory failed to retain assay sheets for 22 of 24 quality control assay sheets used in 2020 and 2021. The two hematology control assay sheets found were: Lot# 20260710 Exp 04-May-22 Lot# 03370710 Exp 03-Jan-21 2. An interview with the manager on 4/8/22 at 9:24 am in the office confirmed the laboratory did not retain the hematology control assay sheets for a minimum of 2 years. Key: CBC=Complete Blood Count QC=Quality Control</p>
<p>D5413</p>	<p>Based on the review of the manufacturer's instructions for use, the laboratory's temperature and humidity logs from 2020-2021, and confirmed in an interview found the laboratory failed to document the operating room temperature and humidity as required by the manufacturer for 24 of 24 months on one of one Sysmex XP-300 hematology instrument. The findings were: 1. Review of the manufacturer's manual titled Sysmex Automated Hematology Analyzer XP-300 Instructions for Use (North American Edition) (Code No. AU553517. Date of Last Revision: June 2013. Software Version: 00-12 and onwards.) in chapter 14. Technical Information 14.1 Specification revealed the operating environment in ambient temperature was 15C-30C and relative humidity was 30% to 85%. 2. Review of the laboratory's temperature and humidity logs from 2020-2021 revealed no documentation of the required operating temperature and humidity for 24 of 24 months. 3. Review of CMS 116 signed by the LD on 3/30/2022 revealed the annual volume for Sysmex XP-300 hematology instrument was 415. 4 An interview with the manager on 4/7/22 at 11:45 am in the office confirmed the above findings. The manager stated the facility did not have temperature and humidity logs. Key: CMS=Center of Medicare and Medicaid Service LD=Laboratory Director</p>
<p>D5429</p>	<p>Based on the review of the manufacturer's manual, the laboratory's maintenance records from 2020-2021, CMS 116 records, and confirmed in an interview found the laboratory failed to perform and document maintenance as defined by the manufacturer's instructions for 24 of 24 months for one of one Sysmex XP-300 hematology instrument. The findings were: 1. Review of the manufacturer's manual titled Sysmex Automated Hematology Analyzer XP-300 Instructions for Use (North American Edition) (Code No. AU553517. Date of Last Revision: June 2013. Software Version: 00-12 and onwards.) in Chapter 12. Cleaning and Maintenance 12.1 Maintenance schedule revealed daily and weekly maintenance are scheduled for the XP-300 Hematology analyzer (SN#:A5008). Daily Clean TD chambers and diluted sample lines (Shutdown) Check trap chamber level and discard Weekly Clean SRV tray 2. Review of the laboratory's maintenance records from 2020-2021 revealed no documentation of daily and weekly maintenance from 2020-2021. 3. Review of CMS 116 signed by the LD on 3/30/2022 revealed the annual volume for Sysmex XP-300 hematology instrument was 415. 4 An interview with the manager on 4/7/22 at 11:50 am in the office confirmed the above findings. The manager stated the facility did not know the maintenance schedule. Key: CMS=Center of Medicare and Medicaid Service LD=Laboratory Director</p>

<p>D5441</p>	<p>Based on the review of the laboratory's QC records from 2020-2021 and confirmed in an interview found the laboratory failed to have a method in place to monitor quality control values over time to detect shifts and trends for five of five analytes on one of one Sysmex XP-300 hematology instrument. The findings were: 1. Review of the laboratory's QC records from 2020-2021 revealed the laboratory not have a method in place to monitor quality control values over time to detect shifts and trends for five of five analytes on one of one Sysmex XP-300 hematology instrument (SN#: A5008). RBC HCT HGB WBC PLT 2. Review of CMS 116 signed by the LD on 3/30/2022 revealed the annual volume for Sysmex XP-300 hematology instrument was 415. 3. An interview with the manager on 4/7/22 at 12:28 pm in the office confirmed the above findings. Key: QC=Quality Control RBC=Red Blood Cell HCT=Hematocrit HGB=Hemoglobin WBC=White Blood Cell PLT=Platelets CMS=Center of Medicare and Medicaid Service LD=Laboratory Director</p>
<p>D5461</p>	<p>Based on the review of the manufacturer's manual, the laboratory reagent replacement history logs from 9/11/20 to 3/31/22 and confirmed in an interview found the laboratory failed to document a quality control run after a change in a reagent on eight of 15 days reviewed on one of one Sysmex XP-300 hematology instrument. The findings were: 1. Review of the manufacturer's manual titled Sysmex Automated Hematology Analyzer XP-300 Instructions for Use (North American Edition) (Code No. AU553517. Date of Last Revision: June 2013. Software Version: 00-12 and onwards.) in Chapter 4. Reagents revealed two reagents were used in the XP-300 Hematology analyzer (SN#:A5008). Cellpack Stromatolyser-WH 2. Random review of the reagent replacement history logs from 9/11/20 to 3/31/22 revealed eight of 15 days reviewed with no documentation of the quality control run after the following reagent change on the Sysmex XP-300 (SN#A5008) hematology analyzer. 9/11/20 at 8:41 am Stromatolyser-WH Lot#Y0002 Exp 2/21/2021 10/12/21 at 9:56 am Stromatolyser-WH Lot#Y1002 Exp 4/29/2022 10/19/21 at 10:56 am Cellpack Lot#Y1008 Exp 1/30/2023 11/16/21 at 10:06 am Cellpack Lot#Y1008 Exp 1/30/2023 12/27/21 at 9:38 am Stromatolyser-WH Lot#Y1002 Exp 4/29/2022 01/14/22 at 10:01 am Cellpack Lot#Y1012 Exp 5/01/2023 3/04/22 at 9:27 am Stromatolyser-WH Lot#Y1002 Exp 4/29/2022 3/09/22 at 10:14 am Cellpack Lot#Y2002 Exp 7/12/2023 3. Review of the patient test records for the above date revealed the laboratory performed eight patient testing after the reagent change above with no documentation of the quality control run. Refer to Patients alias after Reagent Replacement. 4. An interview with the manager on 4/7/22 at 12:25 pm in the office confirmed the above findings.</p>
<p>D5793</p>	<p>Based on the review of the laboratory's policy, the laboratory's QA records from 2020-2021, and confirmed in an interview found the laboratory failed to provide QA records for HHS or its designee review. The findings were: 1. Review of the laboratory's policy titled 1st Choice Pediatrics Quality Assurance Policies and Procedure under D. Quality Assurance Records revealed " All quality assurance records will be maintained by the laboratory for a period of two years and will be made available for review by HHS or its designee." 2. Review of the laboratory's QA records from 2020-2021 revealed no documentation of QA check list for QA indicators from 2020-2021. 3. An interview with the manager on 4/7/22 at 12:00 pm in the office confirmed the above findings. The manager could not provide any QA records for review. Key: QA=Quality Assurance</p>
<p>D5807</p>	<p>Based on the review of the laboratory's final reports and confirmed in an interview found the laboratory failed to provide the reference ranges or reference intervals to the authorized person who ordered the test for one of one Sysmex XP-300 hematology</p>

	<p>instrument. The findings were: 1. Review of the laboratory's final reports revealed no reference ranges or reference intervals were provided to the authorized person who ordered the test for one of one Sysmex XP-300 hematology instrument (SN# A5008). 2. Review of CMS 116 signed by the LD on 3/30/2022 revealed the annual volume for Sysmex XP-300 hematology instrument was 415. 3. An interview with the manager on 4/8/22 at 10:00 am in the office confirmed the above findings. Key: CMS=Center of Medicare and Medicaid Service LD=Laboratory Director</p>
<p>D6018</p>	<p>Based on the review of the laboratory's policy, API proficiency test results from 2020-2021 and confirmed in an interview found the LD failed to document the evaluation and verification for one of six PT events in 2020 Hematology/Coagulation-1st event. The findings were: 1. Review of the laboratory's policy titled 1st Choice Pediatrics Quality Assurance Policies and Procedure under B. Quality Assurance Indicators 3. Proficiency Testing revealed "All proficiency test results will be reviewed and corrective actions will be taken for any failures. 2. Review of the laboratory's API Hematology/Coagulation proficiency testing records from 2020 to 2021 revealed no documentation of evaluation and verification by the LD for one of six PT events. 2020 Hematology/Coagulation-1st event 3. Review of the API proficiency test results for the 2020 Hematology/Coagulation-1st event revealed six of six regulated analytes received unacceptable performance in 2020 Hematology/Coagulation-1st event. (Refer to D2121) 4. An interview with RN on 4/7/22 at 10:15 am in the office confirmed the above findings. Key: API= American Proficiency Institute LD=Laboratory Director PT=Proficiency testing</p>
<p>D6019</p>	<p>Based on the review of the laboratory's policy, API proficiency test results from 2020-2021 and confirmed in an interview found the LD failed to document of corrective actions for one of six PT events in 2020 Hematology/Coagulation-1st event. The findings were: 1. Review of the laboratory's policy titled 1st Choice Pediatrics Quality Assurance Policies and Procedure under B. Quality Assurance Indicators 3. Proficiency Testing revealed "All proficiency test results will be reviewed and corrective actions will be taken for any failures. 2. Review of the laboratory's API Hematology/Coagulation proficiency testing records from 2020 to 2021 revealed no documentation of corrective actions for the unacceptable performance of six of six regulated analytes by the LD for one of six PT events. 2020 Hematology/Coagulation-1st event 3. Review of the API proficiency test results for the 2020 Hematology /Coagulation-1st event revealed six of six regulated analytes received unacceptable performance in 2020 Hematology/Coagulation-1st event. Erythrocyte Count Hematocrit Hemoglobin Leukocyte Count Platelets White Blood Cell Differential 4. An interview with RN on 4/7/22 at 10:15 am in the office confirmed the above findings. Key: API= American Proficiency Institute LD=Laboratory Director PT=Proficiency testing</p>
<p>D6067</p>	<p>Based on the review of the laboratory's training records and confirmed in an interview found the laboratory failed to document training records prior to perform and report patient test results for one of four TP on one of one Sysmex XP-300 hematology instrument. The findings were: 1. Review of the laboratory's training records revealed no documentation of training records prior to perform and report patient test results for one of four TP on one of one Sysmex XP-300 hematology instrument (SN#: A5008). TP#3 (based on CMS 209 signed by the LD on 3/30/22) Hired Date: 6/15 /2020 2. An interview with the manager and TP#3 on 4/7/22 at 9:55 am in the office confirmed the above findings. TP#3 confirmed to perform and report patient test results independently starting on February 2020. Key: TP=Testing personnel CMS=Center of Medicare and Medicare Service LD= Laboratory Director</p>