

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0994691	(X3) Date Survey Completed 02/03/2026
Name of Provider or Supplier All Children's Pediatric Clinic P A	Street Address, City, State 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
D2010	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2)</p> <p>(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, review of the laboratory's American Proficiency Testing Institute's proficiency testing records from 2023, 2024, and 2025, and staff interview, the laboratory failed to test proficiency testing samples the same number of times it routinely tested patient samples for 6 of 7 events. The findings included: 1. The laboratory's policy titled "Proficiency Testing" (approved 9/1/2014) stated: "PT specimens are to be treated the same as patient samples." 2. The laboratory's policy titled "Critical Values" (approved 6/15/2025) stated: "The Laboratory Personnel will repeat all CBC's outside the critical/panic value range..." The policy then defined the following ranges: White blood cell under 2.0 or over 22.0 Hemoglobin under 7.5 or over 18 Hematocrit under 24 or over 55 Platelet under 50 or over 800 3. A review of the laboratory's American Proficiency Institute's proficiency testing records from 2023 (event 3), 2024 (events 1, 2 and 3) and 2025 (events 1, 2 and 3) determined the laboratory tested proficiency samples multiple times that did not meet the defined criteria for repeat testing on 6 of 7 events. They were: a) 2023 event 3 Sample: HSY - 012 tested: 11/17/2023 @ 10:11 tested: 11/17/2023 @ 10:12 Sample: HSY-15 tested: 11/17/2023 @ 10:19 tested: 11/17/2023 @ 10:20 b) 2024 event 1 Sample: HSY - 01 tested: 03/18/2024 @ 10:44 tested: 03/18/2024 @ 10:46 c) 2024 event 2 Sample: HSY - 07 tested: 07/18/2024 @ 09:37 tested: 07/18/2024 @ 09:38 Sample: HSY-08 tested: 07/18/2024 @ 09:40 tested: 07/18/2024 @ 09:41 d) 2024 event 3 Sample: HSY-11 tested: 11/14/2024 @ 14:09 tested: 11/14/2024 @ 14:10 Sample: HSY-13 tested: 11/14/2024 @ 14:12 tested: 11/14/2024 @ 14:15 Sample: HSY-15 tested: 11/14/2024 @ 14:21 tested: 11/14/2024 @ 14:22 e) 2025 event 1 Sample: HSY-01 tested: 03/12/2025 @ 09:42 tested: 03/12/2025 @ 09:45 Sample:</p>

HSY-04 tested: 03/12/2025 @ 09:59 tested: 03/12/2025 @ 10:05 f) 2025 event 1
Sample: HSY-07 tested: 07/09/2025 @ 11:22 tested: 07/09/2025 @ 11:23 Sample:
HSY-10 tested: 07/09/2025 @ 11:34 tested: 07/09/2025 @ 11:35 4. The technical
consultant confirmed the findings in an interview conducted on 02/03/2026 at 0900
hours in exam room 4.

D5411

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

(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 the manufacturer's instructions for the the Sysmex XP-300 hematology analyzer, review of patient test results from January 2026, and staff interview, the laboratory failed to have documentation of following the manufacturer's instructions for the resolution of flagged differential results prior to reporting to the provider. The findings included: 1. The manufacturer's instructions for the Sysmex XP-300 hematology analyzer (Code No. AU553517, revision date: May 2014) under the section titled "Histogram flags" stated: "Various information can be obtained from the histograms. The XP-300 extracts the characteristics of the histogram and displays them as histogram flags. When the histogram flags are displayed, perform analysis again. If afterwards the flags are still displayed, the sample is considered to correspond to one of the following: 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: Centrifuge sample and replace the plasma with equal volume of saline or CELLPACK and repeat analysis. Check smear, etc." 2. A sampling of patient results from January 2026 identified the following patient results reported to the provider without documentation of corrective actions for flagged differential results. Test date: 01/13/2026 Date of Birth: 8/24/2012 Flag: WL Test date: 01/14/2026 Date of Birth: 12/2/2013 Flag: WL Test date: 01/14/2026 Date of Birth: 10/22/2008 Flag: WL Test date: 01/15/2026 Date of Birth: 1/25/2011 Flag: WL Test date: 01/15/2026 Date of Birth: 12/2/2004 Flag: WL Test date: 01/18/2026 Date of Birth: 10/4/2019 Flag: WL Test date: 01/19/2026 Date of Birth: 09/16/2000 Flag: WL Test date: 01/20/2026 Date of Birth: 3/20/2013 Flag: WL Test date: 01/20/2026 Date of Birth: 12/30/2015 Flag: WL Test date: 01/20/2026 Date of Birth: 10/18/2016 Flag: WL Test date: 01/20/2026 Date of Birth: 09/10/2019 Flag: WL Test date: 01/22/2026 Date of Birth: 06/16/2011 Flag: WL Test date: 01/23/2026 Date of Birth: 04/07/2008 Flag: WL Test date: 01/25/2026 Date of Birth: 2/1/2018 Flag: WL Test date: 01/27/2026 Date of Birth: 4/20/2009 Flag: WL Test date: 01/28/2026 Date of Birth: 6/15/2013 Flag: WL Test date: 01/30/2026 Date of Birth: 11/4/2017 Flag: WL Test date: 01/31/2026 Date of Birth: 7/16/2014 Flag: WL 3. The technical consultant confirmed the findings in an interview conducted on 02/03/2026 at 1000 hours in exam room number 4.

D5785

CORRECTIVE ACTIONS
CFR(s): 493.1282(b)(3)

(b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.

This STANDARD is not met as evidenced by:
 Based on review of the laboratory's temperature logs from January 2024 to December 2024, and staff interview, the laboratory failed to have documentation of corrective actions being performed on 26 of 26 days when the documented room temperature was outside the laboratory's acceptable range. The findings included: 1. A review of the laboratory's temperature logs from January 2024 to December 2024 identified the laboratory had a defined acceptable temperature range for room temperature at 59 - 77 F. 2. Further view of the temperature logs identified 26 days where the documented room temperature was outside the laboratory's acceptable range and the laboratory failed to have documentation of performing corrective actions. The days and temperature were: a) February 2024 2/1/2024 Temp: 48F 2/2/2024 Temp: 58F 2/5/2024 Temp: 58F 2/22/2024 Temp: 48F 2/23/2024 Temp: 58F 2/25/2024 Temp: 58F b) March 2024 3/3/2024 Temp: 58F 3/15/2024 Temp: 58F c) April 2024 4/13/2024 Temp: 58F 4/21/2024 Temp: 58F d) May 2024 5/4/2024 Temp: 58F 5/11/2024 Temp: 48F 5/12/2024 Temp: 58F 5/16/2024 Temp: 38F 5/17/2024 Temp: 57F e) June 2024 6/4/2024 Temp: 58F 6/15/2024 Temp: 58F f) July 2024 7/4/2024 Temp: 58F 7/26/2024 Temp: 58F g) August 2024 8/4/2024 Temp: 58F 8/15/2024 Temp: 58F h) September 2024 9/4/2024 Temp: 58F i) October 2024 10/14/2024 Temp: 58F j) December 2024 12/2/2024 Temp: 58F 12/3/2024 Temp: 49F 12/17/2024 Temp: 58F 3. The technical consultant confirmed the findings in an interview conducted on 02/03/2026 at 1015 hours in exam room 4.

D5813

TEST REPORT
 CFR(s): 493.1291(g)

(g) 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.

This STANDARD is not met as evidenced by:
 Based on review of the laboratory's policies, review of patient test records from January 2026, and staff interview, the laboratory failed to have documentation of the notification of 1 of 2 critical values. The findings included: 1. The laboratory's policy titled "Critical Values" (approved 6/15/2025) stated: "The Laboratory Personnel will repeat all CBC's outside the critical/panic value range and immediately notify the provider. Documentation must include: Who was notified, when it was notified time and date, and by whom was the person notified." The policy then defined the following critical ranges: White blood cell under 2.0 or over 22.0 Hemoglobin under 7.5 or over 18 Hematocrit under 24 or over 55 Platelet under 50 or over 800 2. A review of the laboratory's patient test records from January 2026 determined the laboratory failed to have documentation of the date and time of the notification of 1 of 2 critical values. It was: a) Test date: 01/13/2026 Date of birth 7/15/2025 Result: White blood cell = 23.7 3. The technical consultant confirmed the findings in an interview conducted on 02/03/2026 at 0950 hours in exam room 4.

D5891

POSTANALYTIC SYSTEMS QUALITY ASSESSMENT
 CFR(s): 493.1299(a)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems

identified in the postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's Quality Assurance Plan, review of patient test reports and staff interview, the laboratory failed to ensure patient normal ranges were visible on 10 of 18 patient results for accurate physician interpretation of results. The findings included: 1. The laboratory's Quality Assurance Plan (approved 09/01/2014) under the section titled "Patients Test Management" stated: "(POST-ANALYTICAL) That the report contains information the physician needs to interpret the results..." 2. A sampling of patient test records from January 2026 identified 10 of 18 patient results reported to the provider where the required patient normal range for the patient was covered by the instrument printouts. They were: Test date: 01/13/2026 Date of Birth: 8/24/2012 Reference Range 10 - 17 years covered by printout Test date: 01/14/2026 Date of Birth: 12/2/2013 Reference Range 10 - 17 years covered by printout Test date: 01/14/2026 Date of Birth: 10/22/2008 Reference Range 10 - 17 years covered by printout Test date: 01/15/2026 Date of Birth: 1/25/2011 Reference Range 10 - 17 years covered by printout Test date: 01/20/2026 Date of Birth: 12/30/2015 Reference Range 10 - 17 years covered by printout Test date: 01/22/2026 Date of Birth: 06/16/2011 Reference Range 10 - 17 years covered by printout Test date: 01/23/2026 Date of Birth: 04/07/2008 Reference Range 10 - 17 years covered by printout Test date: 01/25/2026 Date of Birth: 2/1/2018 Reference Range 2 - 9 years covered by printout Test date: 01/27/2026 Date of Birth: 4/20/2009 Reference Range 10 - 17 years covered by printout Test date: 01/28/2026 Date of Birth: 6/15/2013 Reference Range 10 - 17 years covered by printout 3. The technical consultant confirmed the findings in an interview conducted on 02/03/2026 at 1005 hours in exam room number 4.