

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2095721	(X3) Date Survey Completed 09/15/2026
Name of Provider or Supplier Dr Karelys Rivera And Associates Pa	Street Address, City, State 3126 Centerpoint Drive, Edinburg, 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing policy, review of the laboratory's Wisconsin State Hygiene Laboratory's proficiency testing records from 2025 and 2026, and staff interview, the laboratory failed to have documentation of testing personnel signing 4 of 5 attestation statements. The findings included: 1. The laboratory's proficiency testing policy stated: "The attestation statement shall be signed and dated by testing personnel and the Laboratory Director at the time of testing." 2. A review of the laboratory's Wisconsin State Hygiene Laboratory's proficiency testing records from 2025 (events 1, 2, and 3) and 2026 (events 1 and 2) determined the laboratory failed to have documentation of each testing personnel signing the attestation statement for 4 of 5 events. They were: 2025 Event 2 2025 Event 3 2026 Event 1 2026 Event 2 3. The technical consultant confirmed the findings in an interview conducted on 09/15/2026 at 900 hours in the break room.
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) (b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing policy, review of the

	laboratory's Wisconsin State Laboratory of Hygiene proficiency testing records from 2025 and 2026, and staff interview, the laboratory failed to test proficiency samples the same number of times it routinely tests patient samples for 4 of 5 events. The findings included: 1. The laboratory's Proficiency Testing policy (signed 10/30/2018) stated: "PT specimens are to be treated the same as patient samples." 2. A review of the laboratory's Wisconsin State Laboratory of Hygiene proficiency testing records from 2025 (Events 1, 2 and 3) and 2026 (Events 1 and) determined the laboratory tested proficiency testing samples more times than it would routinely test patient samples for 4 of 5 events. They were: a) 2025 event 1 Sample: AT 1 Tested: 2/5/2025 2:19 pm Tested: 2.5.2025 2:20 pm No flagged or critical results Sample: AT 2 Tested: 2/5/2026 2:23 pm Tested 2/5/2025 2:24 pm Flagged results on 2nd test b) 2025 event 3 Sample: AT 13 Tested: 9/23/2025 10:45 am Tested: 9/23/2025 10:46 am Sample: AT 15 Tested: 9/23/2026 10:56 am Tested: 9/23/2026 10:59 am No flagged or critical results c) 2026 Event 1 Sample: AT 1 Tested: 02/12/2026 3:53 pm Tested: 02/12/2026 3:55 pm No flagged or critical results d) 2026 Event 2 Sample: AT 7 Tested: 06/10/2026 10:33 am Tested: 06/10/2026 10:35 Flagged results on 2nd test Sample: AT 10 Tested: 06/10/2026 11:00 am Tested: 06/10/2026 11:10 am No flagged or critical results 3. The technical consultant confirmed the findings after her review of the records during an interview conducted on 09/15/2026 at 900 hours in the break room.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, review of the laboratory's Wisconsin State Laboratory of Hygiene proficiency testing records from 2025 and 2026, and staff interview, the laboratory failed to have documentation of evaluating ungraded proficiency testing records on 2 of 5 events. The findings included: 1. The laboratory's Policy titled "Proficiency Testing Corrective Action" stated: "All resulted (sic) labeled as not-graded by the Proficiency Testing Agency will be self-graded and evaluated by the laboratory staff and Technical Consultant." 2. A review of the laboratory's Wisconsin State Laboratory of Hygiene proficiency testing records from 2025 (events 1, 2 and 3) and 2026 (events 1 and 2) identified 2 of 5 events with ungraded results which were not evaluated by the laboratory. They were: a) 2025 event 2 Sample: AT-6 Hemoglobin Hematocrit b) 2026 event 2 Sample: AT-6 Hematocrit Sample: AT-7 Hematocrit Sample: AT-10 Hematocrit 3. The technical consultant confirmed the findings in an interview conducted on 09/15/2026 at 900 hours in the break room.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) 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.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's policies, review of patient test records from August 2026, and staff interview, the laboratory failed to have documentation of repeat testing of 2 of 5 panic values. The findings included: 1. The laboratory's policy titled "Panic Values" stated: "All panic values must be repeated and communicated to the physician immediately. Please document who, when, and what was communicated. Please include your initials." The policy defined the following panic values: White blood cell less than 2 or greater than 22 Hemoglobin less than 8 or greater than 18 Platelet less than 100 or greater than 500 2. A review of the patient test records from August 2026 determined the laboratory failed to have documentation of repeat testing of 2 of 5 panic values. They were: a) August 12, 2026 Patient ID: 08.09.22 Result: PLT 537 b) August 17, 2026 Patient ID: 1.27.25 Result: PLT 564 3. The technical consultant confirmed the finding in an interview conducted on 09/15 /2026 at 1030 hours in the break room.

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 Cell Dyn Emerald hematology analyzer, review of the laboratory policies, review of patient test records from August 2026 and staff interview, the laboratory failed to follow the manufacturer' instructions for resolving flags on ___ of ___ complete blood cell count results. The findings included: 1. The manufacturer's instructions for the Cell Dyn Emerald hematology analyzer (9140847G - November 2013) under the section titled "Table 3.4 WBC Flags" stated: a) Flag: L1 "Check the specimen for clots or agglutination. Follow your laboratory's review criteria or review a stained smear to confirm the differential results and verify the WBC count. Redraw and retest the specimen as required." b) Flag: L2 "Check the Specimen for clots or agglutination. Follow your laboratory's review criteria or review a stained smear to confirm the differential results. Redraw and retest the specimen as required." c) Flag: L3 "Check the Specimen for clots or agglutination. Follow your laboratory's review criteria or review a stained smear to confirm the differential results. Redraw and retest the specimen as required." d) Flag: L5 "Check the specimen for clots or agglutination. Follow your laboratory's review criteria or review a stained smear to confirm the differential results and verify the WBC count. Redraw and retest the specimen as required." 2. The laboratory's policy titled "Policy for Handling Flagged CBC Differentials" stated: "It will be the policy of this laboratory to return (sic) flagged CBC results. If the second run still shows flags, then lab will evaluated flagged differentials according [to] the procedures in the unit's operator manual." 3. A review of testing records from August 2026 identified ___ of ___ flagged patient results which were reported to the provider without the laboratory performing any corrective actions. They were: a) Date: 8/11/2026 ID: 12.8.11 Flag: L1 b) Date: 8/18/2026 ID: 11.8.11 Flag: L1 c) Date: 8/18/2026 ID: 11.8.11 Flag: L1 d) Date: 8/18/2026 ID: 4.25.25 Flags: L1; L5 e) Date: 8/25/2026 ID: 10.04.11 Flag: L1 f) Date: 8/26/2026 ID: 12.25.12 Flag: L1 g) Date: 8/26/2026 ID: 11.23.2026 Flag: L3 h) Date: 8/27/2026 ID:

	08.19.2026 Flag: L1 i) Date: 8/28/2026 ID: 07.17.19 Flags: L2, L3 j) Date: 08/28/2026 ID: 06.10.15 Flag: L1 k) Date: 08/28/2026 ID: 08.13.20 Flag: L1 l) Date: 08/28/2026 ID: 06.10.15 Flag: L1 4. The technical consultant confirmed the findings after her review of the records in an interview conducted on 09/15/2026 at 1015 hours in the break room.
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 August 2026, and staff interview, the laboratory failed to have documentation of the notification of 5 of 5 panic values. The findings included: 1. The laboratory's policy titled "Panic Values" stated: "All panic values must be repeated and communicated to the physician immediately. Please document who, when, and what was communicated. Please include your initials." The policy defined the following panic values: White blood cell less than 2 or greater than 22 Hemoglobin less than 8 or greater than 18 Platelet less than 100 or greater than 500 2. The laboratory's policy titled "Reporting Critical Values" stated: "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 the patient test records from August 2026 determined the laboratory failed to have documentation of the notification of 5 of 5 panic values. They were: a) August 3, 2026 Patient ID: 6.9.20 Result: PLT 589 b) August 11, 2026 Patient ID: 12.8.11 Result: PLT 551 c) August 12, 2026 Patient ID: 08.09.22 Result: PLT 537 d) August 17, 2026 Patient ID: 1.27.25 Result: PLT 564 e) August 21, 2026 Patient ID: 10.9.13 Result: Hemoglobin 7.5 4. The technical consultant confirmed the finding in an interview conducted on 09/15/2026 at 1030 hours in the break room.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on review of the laboratory's quality assurance plan, review of the laboratory's quality assurance records from November 2024 to August 2026, and staff interview, the laboratory director failed to document her review of the monthly quality assurance records for 22 of 22 months. The findings included: 1. A review of the laboratory's quality assurance plan (approved 10/30/2018) under the section titled "Quality Assurance Records" identified the plan stated: "All records are dated and initialed by the staff performing the review, by the Technical Consultant, and by the Laboratory Director." 2. A review of the laboratory's quality assurance records from November 2024 to August 2026 determined the laboratory director failed to initial and date 22 of 22 months worth of quality assurance records. 3. The technical consultant confirmed

the findings in an interview conducted on 09/15/2026 at 1045 hours in the break room.