

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2183279	(X3) Date Survey Completed 08/21/2026
Name of Provider or Supplier Radiance Diagnostics	Street Address, City, State 1240 Iroquois Ave - Ste 300, Naperville, IL	
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	Based on review of laboratory records and a proficiency testing review of the College of American Pathologists (CAP) Proficiency Testing (PT) records provided by CAP via email on 08/05/2026 at 3:28 pm; the laboratory was out of compliance with the 42 C.F.R. Part 493 CLIA requirements for the following CONDITION level deficiencies: D2016 - 42 C.F.R. 493.803 Condition: Successful participation [proficiency testing]; D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director.
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of laboratory records and a proficiency testing review of the College

of American Pathologists (CAP) Proficiency Testing (PT) records provided by CAP via email on 08/05/2026 at 3:28 pm; the laboratory failed to successfully participate in their PT program for the routine chemistry analytes Ferritin, Low-Density Lipoprotein (LDL), Lactate Dehydrogenase (LDH), and Uric Acid; and for the subspecialty of Endocrinology overall and endocrinology analytes Free Thyroxine (FT4), Thyroid Stimulating Hormone (TSH), Total Triiodothyronine (TT3), and Cortisol for the following PT events in 2025 and 2026. See D2096 (a and b), D2107, and D2108.

D2096

ROUTINE CHEMISTRY

CFR(s): 493.841(f)

(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

A) Based on review of laboratory records, a proficiency testing review of the College of American Pathologists (CAP) Proficiency Testing (PT) records provided by CAP, and interview with the laboratory owner; the laboratory failed to achieve satisfactory performance for the routine chemistry analytes Lactate Dehydrogenase (LDH) for two consecutive PT events in 2026 (Event 1 of 2026 and Event 2 of 2026) and Uric Acid for two consecutive PT events in 2025 (Event 1 of 2025 and Event 2 of 2025) resulting in the initial unsuccessful PT performances for LDH and Uric Acid analytes in the subspecialty of routine chemistry. Findings include: 1. Review of laboratory CAP PT records revealed the laboratory received the following unsatisfactory scores for routine chemistry analytes LDH and Uric Acid. LDH Event 1 of 2026 - 60% Unsatisfactory Event 2 of 2026 - 0% Unsatisfactory Uric Acid Event 1 of 2025 - 0% Unsatisfactory Event 2 of 2025 - 0% Unsatisfactory 2. Review of CAP PT evaluation reports for Routine Chemistry Event 1 (C-A) 2025, Event 2 (C-B) 2025, Event 1 (C-A) 2026, and Event 2 (C-B) 2026, received via email from CAP on 08/05/2026, at 3:28 pm, confirmed the above unsatisfactory scores that resulted in the initial unsuccessful PT performance for the routine chemistry analytes LDH and Uric Acid. 3. Interview with the laboratory owner on 07/29/2025, at 11:03 am, revealed that the laboratory had not tested PT samples because the laboratory failed to procure the required reagents at the time of PT events and that the laboratory had continued to test patient samples during this time when the laboratory was able to obtain the required reagents. B) Based on review of laboratory records, a proficiency testing review of the College of American Pathologists (CAP) Proficiency Testing (PT) records provided by CAP, and interview with the laboratory owner; the laboratory failed to achieve satisfactory performance for the routine chemistry analytes Ferritin for three consecutive PT events in 2025 (Event 1 of 2025, Event 2 of 2025, and Event 3 of 2025) and Low-Density Lipoprotein (LDL) for three consecutive PT events in 2025 and 2026 (Event 3 of 2025, Event 1 of 2026, and Event 2 of 2026) resulting in the subsequent unsuccessful PT performances for Ferritin and LDL analytes in the subspecialty of routine chemistry. Findings include: 1. Review of laboratory CAP PT records revealed the laboratory received the following unsatisfactory scores for routine chemistry analytes Ferritin and LDL. Ferritin Event 1 of 2025 - 0% Unsatisfactory Event 2 of 2025 - 0% Unsatisfactory Event 3 of 2025 - 0% Unsatisfactory LDL Event 3 of 2025 - 0% Unsatisfactory Event 1 of 2026 - 0% Unsatisfactory Event 2 of 2026 - 0% Unsatisfactory 2. Review of CAP PT evaluation reports for Routine Chemistry Event 1 (C-A) 2025, Event 2 (C-B) 2025, Event 3 (C-C) 2025, Event 1 (C-A) 2026, and Event 2 (C-B) 2026, received via email from CAP

	on 08/05/2026, at 3:28 pm, confirmed the above unsatisfactory scores that resulted in the subsequent unsuccessful PT performance for the routine chemistry analytes Ferritin and LDL. 3. Interview with the laboratory owner on 07/29/2025, at 11:03 am, revealed that the laboratory had not tested PT samples because the laboratory failed to procure the required reagents at the time of PT events and that the laboratory had continued to test patient samples during this time when the laboratory was able to obtain the required reagents.
D2107	ENDOCRINOLOGY CFR(s): 493.843(f) (f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of laboratory records, a proficiency testing review of the College of American Pathologists (CAP) Proficiency Testing (PT) records provided by CAP, and interview with the laboratory owner; the laboratory failed to achieve satisfactory performance for the endocrinology analytes Free Thyroxine (FT4) for five consecutive PT events in 2025 and 2026 (Event 1 of 2025, Event 2 of 2025, Event 3 of 2025, Event 1 of 2026, and Event 2 of 2026), Thyroid Stimulating Hormone (TSH) for three consecutive PT events in 2025 (Event 1 of 2025, Event 2 of 2025, and Event 3 of 2025), Total Triiodothyronine (TT3) for four of five consecutive PT events (Event 1 of 2025, Event 2 of 2025, Event 3 of 2025, and Event 2 of 2026), and Cortisol for three consecutive PT events in 2025 (Event 1 of 2025, Event 2 of 2025, and Event 3 of 2025) resulting in the subsequent unsuccessful PT performances for FT4, TSH, TT3, and Cortisol analytes in the subspecialty of endocrinology. Findings include: 1. Review of laboratory CAP PT records revealed the laboratory received the following unsatisfactory scores for endocrinology analytes FT4, TSH, TT3, and Cortisol. FT4 Event 1 of 2025 - 0% Unsatisfactory Event 2 of 2025 - 0% Unsatisfactory Event 3 of 2025 - 0% Unsatisfactory Event 1 of 2026 - 0% Unsatisfactory Event 2 of 2026 - 0% Unsatisfactory TSH Event 1 of 2025 - 0% Unsatisfactory Event 2 of 2025 - 0% Unsatisfactory Event 3 of 2025 - 0% Unsatisfactory TT3 Event 1 of 2025 - 0% Unsatisfactory Event 2 of 2025 - 0% Unsatisfactory Event 3 of 2025 - 0% Unsatisfactory Event 2 of 2026 - 0% Unsatisfactory Cortisol Event 1 of 2025 - 0% Unsatisfactory Event 2 of 2025 - 0% Unsatisfactory Event 3 of 2025 - 0% Unsatisfactory 2. Review of CAP PT evaluation reports for Endocrinology Event 1 (C-A) 2025, Event 2 (C-B) 2025, Event 3 (C-C) 2025, Event 1 (C-A) 2026, and Event 2 (C-B) 2026, received via email from CAP on 08/05/2026, at 3:28 pm, confirmed the above unsatisfactory scores that resulted in the subsequent unsuccessful PT performance for the endocrinology analytes FT4, TSH, TT3, and Cortisol. 3. Interview with the laboratory owner on 07/29/2025, at 11:03 am, revealed that the laboratory had not tested PT samples because the laboratory failed to procure the required reagents at the time of PT events and that the laboratory had continued to test patient samples during this time when the laboratory was able to obtain the required reagents.
D2108	ENDOCRINOLOGY CFR(s): 493.843(g) (g) Failure to achieve an overall testing event score of satisfactory performance for

	two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of laboratory records, a proficiency testing review of the College of American Pathologists (CAP) Proficiency Testing (PT) records provided by CAP, and interview with the laboratory owner; the laboratory failed to achieve satisfactory performance for the subspecialty of Endocrinology overall for four of five consecutive PT events (Event 1 of 2025, Event 2 of 2025, Event 3 of 2025, and Event 2 of 2026) resulting in the subsequent unsuccessful PT performance for Endocrinology. Findings include: 1. Review of laboratory CAP PT records revealed the laboratory received the following unsatisfactory scores for the subspecialty of Endocrinology. Endocrinology (OVERALL) Event 1 of 2025 - 0% Unsatisfactory Event 2 of 2025 - 0% Unsatisfactory Event 3 of 2025 - 0% Unsatisfactory Event 2 of 2026 - 57% Unsatisfactory 2. Review of CAP PT evaluation reports for Endocrinology Event 1 (C-A) 2025, Event 2 (C-B) 2025, Event 3 (C-C) 2025, and Event 2 (C-B) 2026, received via email from CAP on 08/05/2026, at 3:28 pm, confirmed the above unsatisfactory scores that resulted in the subsequent unsuccessful PT performance for the subspecialty of Endocrinology. 3. Interview with the laboratory owner on 07/29/2025, at 11:03 am, revealed that the laboratory had not tested PT samples because the laboratory failed to procure the required reagents at the time of PT events and that the laboratory had continued to test patient samples during this time when the laboratory was able to obtain the required reagents.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of laboratory records, a proficiency testing review of the College of American Pathologists (CAP) Proficiency Testing (PT) records provided by CAP, and interview with the laboratory owner; the laboratory director failed to ensure successful participation in their PT program for the routine chemistry analytes Ferritin, Low-Density Lipoprotein (LDL), Lactate Dehydrogenase (LDH), and Uric Acid; and for the subspecialty of Endocrinology overall and endocrinology analytes Free Thyroxine (FT4), Thyroid Stimulating Hormone (TSH), Total Triiodothyronine (TT3), and Cortisol for the following PT events in 2025 and 2026. See D6089.
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) (e)(4)(i) The proficiency testing samples are tested as required under subpart H of this part; This STANDARD is not met as evidenced by: Based on review of laboratory records, a proficiency testing review of the College of American Pathologists (CAP) Proficiency Testing (PT) records provided by CAP, and

interview with the laboratory owner; the laboratory director failed to ensure successful participation in their PT program for the routine chemistry analytes Ferritin, Low-Density Lipoprotein (LDL), Lactate Dehydrogenase (LDH), and Uric Acid; and for the subspecialty of Endocrinology overall and endocrinology analytes Free Thyroxine (FT4), Thyroid Stimulating Hormone (TSH), Total Triiodothyronine (TT3), and Cortisol for the following PT events in 2025 and 2026. See D2096, D2107, and D2108.