Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2275789	01/06/2026
Name of Provider or Supplier	**Street Address, City, State**	
Ivf-Pgt Lab Oakbrook	1919 Midwest Road, Ste 100, Oak Brook, 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	A recertification survey was completed on 01/06/2026. Noncompliance was found for the following condition level deficiencies: D5020 493.1212 Condition: Endocrinology. D6000 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director.
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 policies and procedures, American Association of Bioanalysts -Medical Laboratory Evaluation (AAB-MLE) proficiency testing (PT) records, lack of documentation, and interview with laboratory representative (LR); the laboratory failed to maintain a copy of all records related to proficiency testing for four of four Endocrinology testing events from the last event of 2024 through 2025, to the date of the on-site survey, 01/06/2026. Findings include: 1. Review of policies and procedures revealed the procedure titled "Proficiency Testing", under "3: Procedures" and "4. PT Evaluation", which stated, "3.2 Testing and reporting ... - Testing personal must enter test results online and on paper, and document reporting by signing on the paper report form - Lab Director or designee must review the results before submitting the results to ABB, just as patient testing". "3.4Attestation page - The proficiency testing attestation statement is signed by the laboratory director or designee and the individual performing the testing before submission." 2. Review of AAB-MLE PT records revealed the laboratory failed to maintain a copy of the LD signature on attestation documents and laboratory director review of AAB-MLE scores for four of four events from the last event of 2024 through 2025: PT Event: 2024 M3 2025 M1 2025 M2 2025 M3 3. Interview with the laboratory representative,

	on survey date 01/06/2026, at 1:15 pm, confirmed the laboratory failed to maintain a copy of all records related to proficiency testing for four of four endocrinology testing events from the last event of 2024 through 2025, to the date of the on-site survey, 01 /06/2026.
D2105	ENDOCRINOLOGY CFR(s): 493.843(e) (e)(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, American Association of Bioanalysts-Medical Laboratory Evaluation (AAB-MLE) proficiency testing (PT) records, lack of documentation, and interview with the laboratory representative (LR); the laboratory failed to perform and document a corrective action for quantitative human chorionic gonadotropin (hCG), one of two unacceptable performance analyte scores, for in AAB-MLE PT event M1 of 2025. Findings include: 1. Review of policies and procedures revealed the procedure titled "Proficiency Testing", under "4. PT Evaluation", which stated, "- Records of PT Testing, including investigation of "unacceptable" PT and alternative assessment results and corrective action, are timely reviewed by the laboratory director or designee ..." 2. Review of AAB-MLE Fertility Testing PT records for event M1 of 2025 found no documented review and corrective action for unacceptable quantitative human chorionic gonadotropin (hCG) score. PT Event: Analyte: Score(%): 2025 M1 hCG 60 3. Interview with the laboratory representative, on survey date 01/06/2026, at 1:15 pm confirmed the laboratory failed to perform and document corrective action for unacceptable performance for hCG in PT event 1 of 2025
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) (a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, laboratory records, lack of documentation, and interview with laboratory representative (LR); the laboratory failed to retain a signed copy of American Association of Bioanalysts -Medical Laboratory Evaluation (AAB-MLE) proficiency testing (PT) records in the subspecialty of endocrinology for one of four events performed from 2024 and 2025 for a minimum of two years from the date of the PT event, as required per 493.1105. Findings include: 1. Review of policies and procedures revealed the procedure titled "Proficiency Testing", under "3: Procedures", "3.2 Testing and reporting" which stated, "Primary records related to PT and alternative assessment testing are retained for two years." 2. Review of laboratory PT documents from 2024 revealed the

	laboratory failed to retain primary records related to PT including attestations and review of results signed by the LD for event M3 of 2024. 3. Interview with the laboratory representative, on survey date 01/06/2026, at 6:04 pm, confirmed the laboratory failed to retain all PT records for in the subspecialty of endocrinology for one of four events (M3 of 2024) performed from 2024 and 2025 for a minimum of two years from the date of the PT event.
D5020	ENDOCRINOLOGY CFR(s): 493.1212 If the laboratory provides services in the subspecialty of Endocrinology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records, patient test reports, lack of documentation, and interviews with the laboratory representative (LR); the laboratory failed to ensure corrective actions were documented for ten of ten unacceptable or unsatisfactory PT sample results in 2025 through the date of survey, 01/06/2026 (See D5211). Secondly, the laboratory failed to perform quality control (QC) procedures for acceptability specified by the laboratory for endocrinology testing on the TOSOH AiA-360 (Serial Number: 2A482812) for 12 of 42 dates reviewed in 2024 (See D5445- A). Likewise, laboratory failed to follow QC procedures for acceptable Standard Deviations (SD) ranges specified by the laboratory for endocrinology testing on the TOSOH AiA-360 for three of three "AIA-System Control Data" monthly QC charts reviewed in 2025, affecting 36 patients (See D5445-B); and the laboratory failed follow QC procedures specified by the laboratory for two of two control lot change-over reviewed for endocrinology testing on the TOSOH AiA-360 (See D5445- C). Lastly, the laboratory failed to meet the criteria for acceptability of quality control (QC) results prior to reporting patient test results as required per 493.1256 for 12 of 42 patient testing dates reviewed in the months of May and September of 2024 for endocrine testing using TOSOH AiA-360, affecting 19 patient results (See D5481).
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, American Association of Bioanalysts-Medical Laboratory Evaluation (AAB-MLE) proficiency testing (PT) records, lack of documentation, and interview with the laboratory representative (LR); the laboratory failed to identify, perform and document corrective actions for six of ten unacceptable or unsatisfactory PT sample results in 2025 through the date of survey, 01/06/2026. Findings include: 1. Review of policies and procedures revealed the procedure titled "Proficiency Testing", under "4. PT Evaluation", which stated, "-Records of PT Testing, including investigation of "unacceptable" PT and alternative assessment results and corrective action, are timely reviewed by the laboratory director or designee ..." 2. Review of AAB-MLE PT records revealed the following

	ten unacceptable or unsatisfactory PT sample results lacked corrective action documentation: PT Event: Analyte: Sample: 2025 M1 ES2 * 3 2025 M1 Prog *** 5 2025 M1 hCG ^* 4 2025 M1 hCG ^* 5 2025 M2 Prog *** 7 2025 M3 hCG ^* 11 *ES2 = Estradiol; ***Prog = Progesterone; ^*hCG = Human Chorionic Gonadotropin (quantitative hCG) 3. Review of PT records found no corrective action documentation for the unsatisfactory scores for three of three events of 2025. 4. Interview with the laboratory representative, on survey date on 01/06/2026, at 1:15 pm, confirmed the laboratory failed to ensure corrective action was taken for six of ten unacceptable PT sample results from 2025 through the date of survey, 01/06/2026.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) (d) 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. (d)(3) At least once each day patient specimens are assayed or examined perform the following for: This STANDARD is not met as evidenced by: A. Based on review of laboratory policies and procedures, record review, and interview with the laboratory representative (LR); the laboratory failed to perform quality control (QC) procedures for acceptability specified by the laboratory for endocrinology testing on the TOSOH AiA-360 (Serial Number: 2A482812) for 12 of 42 dates reviewed in 2024. Findings include: 1. Review of policies and procedures revealed the procedure titled "Quality Control", under "II. Process Quality Control: TOSOH maintenance and Quality Control: 3. Daily Control Procedures: g) QC Acceptance/ Rejection Criteria", which stated, "For the IVF-PGT Endocrinology Laboratory, a QC run is accepted of two of the three Levels are within Two Standard Deviations." 2. Review of BIO-RAD Immunoassay Plus Control QC test records identified 27 instances of QC results outside acceptable ranges during a random review of QC data from 2024 through the date of survey, 01/06/2026. QC Test Date: Analyte: Levels Out of Range: 05/10/2024 ES* 1,2,3 05/13/2024 ES 1,3 05/14/2024 ES 1,2 05/15/2024 ES 1,2 05/16/2024 ES 1,2,3 05/10/2024 Prog** 1,2,3 05/13/2024 Prog 1,2,3 05/14/2024 Prog 1,2,3 05/15/2024 Prog 1,2,3 05/16/2024 Prog 1,2,3 05/17 /2024 Prog 1,3 05/10/2024 FSH*** 1,2 05/13/2024 FSH 1,3 05/16/2024 FSH 1,2 05 /07/2024 HCG^* 1,3 05/10/2024 HCG 1,2 09/04/2024 ES* 2,3 09/10/2024 ES 2,3 09 /12/2024 ES 2,3 09/13/2024 ES 2,3 09/16/2024 ES 2,3 09/30/2024 ES 2,3 09/10/2024 Prog** 1,2,3 09/13/2024 Prog 1,2,3 09/10/2024 FSH*** 2,3 09/16/2024 FSH 2,3 09 /30/2024 FSH 2,3 *Estradiol, **Progesterone, ***Follicle Stimulating Hormone, ^*Total Beta Human Chronic Gonadotropin 3. Review of QC records found no evidence of corrective action for QC results outside acceptable ranges in 2024. 4. Interview with the laboratory representative, on survey date 01/06/2026 at 3:50 pm confirmed the laboratory failed to perform QC procedures for acceptability specified by the laboratory for endocrinology testing on the TOSOH AiA-360 for 12 of 42 dates reviewed in 2024. B. Based on review of laboratory policies and procedures, record review, and interview with the laboratory representative (LR); the laboratory failed to follow quality control (QC) procedures for acceptable Standard Deviations (SD)

ranges specified by the laboratory for endocrinology testing on the TOSOH AiA-360 (Serial Number: 2A482812) for three of three "AIA-System Control Data" monthly QC charts reviewed in 2025, affecting 36 patients. Findings include: 1. Review of policies and procedures revealed the procedure titled "Quality Control", under "II. Process Quality Control: TOSOH maintenance and Quality Control: 3. Daily Control Procedures: g) QC Acceptance/ Rejection Criteria", which stated, "For the IVF-PGT Endocrinology Laboratory, a QC run is accepted of two of the three Levels are within Two Standard Deviations [2SD]." 2. Review of laboratory records revealed manufacturer's inserts for BIO-RAD Liquichek Immunoassay Plus Control Levels 1, 2 and 3 QC ranges, which stated under "Assignment of Values", "The mean values and corresponding 3SD ranges in the Assignment of Values Data Charts (available separately) were derived from replicate analyses and are specific for this lot of products". 3. Further review of BIO-RAD Immunoassay Plus Control QC test records identified manufacturer's reference 3SD ranges were used for QC acceptance ranges for three of three monthly QC charts reviewed in 2025 affecting 36 patients. Date of testing: Patient ID# 03/28/2025 33355744 03/28/2025 33432104 03/28/2025 300090998_IHR 03/28/2025 33360410 03/28/2025 33389402 03/28/2025 33376137 03/28/2025 33362055 03/28/2025 33455006 03/28/2025 33366441 03/28/2025 33442501 03/28/2025 33349820_M 03/28/2025 33355154 03/28/2025 33421907 03 /28/2025 33441905 03/28/2025 33413195 03/28/2025 33437186 03/28/2025 33365213 07/24/2025 33378096 07/24/2025 33400259 07/24/2025 33457982 07/24 /2025 33453620 07/24/2025 33404450 07/24/2025 33404813 12/26/2025 33439364 12/26/2025 33437780 12/26/2025 33457086 12/26/2025 L270683* 12/26/2025 33360164 12/26/2025 33460360 12/26/2025 33371653 12/26/2025 33464611 12/26 /2025 33453620 12/26/2025 33460857 12/26/2025 33400226 12/26/2025 33404813 12/26/2025 33464323 * Accession Number 4. Interview with the laboratory representative, on survey date 01/06/2026 at 3:50 pm confirmed 3SD ranges were used for QC acceptance ranges were used in 2025 and the laboratory failed to follow quality control (QC) procedures for acceptable Standard Deviations (SD) ranges specified by the laboratory for endocrinology testing on the TOSOH AiA-360 (Serial Number: 2A482812) for three of three "AIA-System Control Data" monthly QC charts reviewed in 2025, affecting 36 patients. C. Based on review of laboratory policies and procedures, record review, and interview with the laboratory representative (LR); the laboratory failed to perform quality control (QC) procedures specified by the laboratory for two of two control lot change-over reviewed for endocrinology testing on the TOSOH AiA-360. Findings include: 1. Review of policies and procedures revealed the procedure titled "Quality Control", under "II. Process Quality Control: TOSOH maintenance and Quality Control: 3. Daily Control Procedures: e) Control lot change-over", which stated, "When a new lot of controls is purchased, the lab will run those controls for 10 data points for each of the three levels in conjunction with the current controls lot to confirm that the new controls are reportable within the range provided by the manufacturer. This allows the lab to make adjustments to the control range prior to use of the new lot of controls. Mean will be calculated from the 10 data points and if the mean calculated is with.in 20% of the manufacturer provided mean then the manufacturer provided control ranges are deemed validated and may be used." 2. Review of BIO-RAD Immunoassay Plus Control QC test records during a random review of QC data from 2024 through the date of survey, 01/06/2026, found the QC switched Test Pack Lots: lot #: 85370 to lot #: 1003900 between 03/07/2025 and 03/10/2025 lot #: 1003900 to lot #: 1003940 10 /20/2025 between 12/15/2025 3. Review of QC records found no evidence of lot comparison or validation for QC results before accepting new lot ranges. 4. Interview with the laboratory representative, on survey date 01/06/2026 at 3:50 pm confirmed the laboratory failed to perform QC procedures specified by the laboratory for control

	lot change-over for endocrinology testing on the TOSOH AiA-360.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratorys and, as applicable, the manufacturers test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview with the laboratory representative; the laboratory failed to meet the criteria for acceptability of quality control (QC) results prior to reporting patient test results as required per 493.1256 for 12 of 42 patient testing dates reviewed in 2024 for endocrine testing using TOSOH AiA-360 (Serial Number: 2A482812), affecting 19 patient results. Findings include: 1. Review of BIO-RAD Immunoassay Plus Control QC data analysis records from May and September of 2024 for the TOSOH AiA-360 showed 12 of 42 testing dates where QC results were outside acceptable ranges for Estradiol, Progesterone, Follicle Stimulating Hormone, or Total Beta Human Chronic Gonadotropin. QC Testing dates: Analyte: Levels Out of Range: 05/07/2024 HCG^* 1,3 05/10/2024 ES* 1,2,3 05/10 /2024 Prog** 1,2,3 05/10/2024 FSH*** 1,2 05/10/2024 HCG 1,2 05/13/2024 ES 1,3 05/13/2024 Prog 1,2,3 05/13/2024 FSH 1,3 05/14/2024 ES 1,2 05/14/2024 Prog 1,2,3 05/15/2024 ES 1,2 05/15/2024 Prog 1,2,3 05/16/2024 ES 1,2,3 05/16/2024 Prog 1,2,3 05/16/2024 FSH 1,2 09/04/2024 ES* 2,3 09/10/2024 ES 2,3 09/10/2024 Prog** 1,2,3 09/10/2024 FSH*** 2,3 09/12/2024 ES 2,3 09/13/2024 ES 2,3 09/13/2024 Prog 1,2,3 09/16/2024 ES 2,3 09/16/2024 FSH 2,3 09/30/2024 ES 2,3 09/30/2024 FSH 2,3 *Estradiol, **Progesterone, ***Follicle Stimulating Hormone, ^*Total Beta Human Chronic Gonadotropin 2. No evidence of repeat testing or corrective action was found for these QC failures. 3. Review of patient testing performed identified 19 patients had endocrinology testing results reported when QC was unacceptable. Testing date: MRN#: Analyte: 05/16/2024 33359645 HCG^* 05/16/2024 33362813 ES, Prog 05/16 /2024 33380069 ES, Prog 05/16/2024 33338540 ES, Prog 05/16/2024 33362055 ES, FSH, HCG^*, Prog 05/16/2024 33363441 ES, Prog 05/16/2024 33368581 ES, FSH, HCG^*, Prog 05/16/2024 33359911 ES, Prog 05/16/2024 33380659 [ES], Prog 09/10 /2024 33362180 ES*, Prog** 09/10/2024 13955 ES, FSH***, Prog 09/10/2024 33349432_M ES, FSH, HCG^*, Prog 09/10/2024 12784 ES, FSH, .Prog 09/10/2024 33400556 ES, FSH, .Prog 09/10/2024 33413195 ES, FSH, .Prog 09/10/2024 11987 ES, FSH, .Prog 09/10/2024 33393890 ES, FSH, .Prog 09/10/2024 33359439 ES, FSH, HCG Prog 09/10/2024 33375047 ES, Prog *Estradiol; **Progesterone; ***Follicle Stimulating Hormone; ^*Total Beta Human Chronic Gonadotropin 4. Interview with the laboratory representative, on survey date 01/06/2026 at 3:02 pm, confirmed the laboratory failed to meet the criteria for acceptability of quality control (QC) results prior to reporting patient test results as required per 493.1256 for 12 of 42 patient testing dates reviewed in the months of May and September of 2024 for endocrine testing using TOSOH AiA-360, affecting 19 patient results.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

	This CONDITION is not met as evidenced by: Based on review of the laboratory's laboratory records, lack of documentation, and interview with laboratory representative (LR); laboratory director (LD) failed to ensure the laboratory documented the LD's on-site visits at least once every six months (See D6005). The LD failed to ensure identified problems that require corrective action and ensure an approved correction plan was followed for unacceptable or unsatisfactory results in the subspecialty of endocrinology (see D6018). The LD failed to ensure the laboratory quality control (QC) procedures are maintained for QC run acceptability, acceptable Standard Deviations ranges, and lot changeovers for endocrinology testing on the TOSOH AiA-360 (See D6020). The LD failed to ensure the laboratory upheld and documented all necessary remedial actions whenever significant deviations from the laboratory's established policies and procedures took place, prior to reporting patient testing results as required per 493. 1256 (See D6024).
D6005	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(c) (c) The laboratory director must: (c)(1) Be onsite at least once every 6 months, with at least 4 months between the minimum two on-site visits. Laboratory directors may elect to be on-site more frequently and must continue to be accessible to the laboratory to provide telephone or electronic consultation as needed; and (c)(2) Provide documentation of these visits, including evidence of performing activities that are part of the laboratory director responsibilities. This STANDARD is not met as evidenced by: Based on review of the laboratory's laboratory records, lack of documentation, and interview with laboratory representative (LR); laboratory director failed to perform and document two on-site visits in 2025, as required per 493.1407. Findings include: 1. Review of laboratory records revealed one of one on-site visit from the acting LD in 2025 documented on 02/14/2025 via a review of quality control (QC) data from January 2025. 2. Interview with the laboratory representative, on survey date 01/06 /2026 at 12:30 pm confirmed the laboratory director failed to perform and document two on-site visits in 2025, as required per 493.1407.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) (e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratorys performance and to identify any problems that require corrective action; and This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the laboratory representative (LR); the LD failed to ensure the laboratory identified, performed and documented corrective actions for six of ten unacceptable or unsatisfactory PT sample results in 2025 through the date of survey, 01/06/2026 (See D5211). The LD also

	failed to ensure the laboratory performed and documented corrective action for quantitative human chorionic gonadotropin (hCG), one of two unacceptable performance analyte scores, for AAB-MLE PT event M1 of 2025 (See D2105).
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 policies and procedures, laboratory records, lack of documentation, and interview with the laboratory representative; the laboratory director (LD) failed to ensure the laboratory performed quality control (QC) procedures for acceptability specified by the laboratory for endocrinology testing on the TOSOH AiA-360 (Serial Number: 2A482812) for 12 of 42 dates reviewed in 2024 (See D5445-A). Likewise, the LD failed to ensure the laboratory followed QC procedures for acceptable Standard Deviations (SD) ranges specified by the laboratory for endocrinology testing on the TOSOH AiA-360 for three of three "AIA-System Control Data" monthly QC charts reviewed in 2025, affecting 36 patients (See D5445-B). The LD also failed to ensure the laboratory followed QC procedures specified by the laboratory for two of two control lot change-over reviewed for endocrinology testing on the TOSOH AiA-360 (See D5445-C).
D6024	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) (e)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratorys established performance specifications are identified, and that patient test results are reported only when the system is functioning properly; This STANDARD is not met as evidenced by: Based on review of the laboratory policies and procedures, laboratory records, lack of documentation, and interview with the laboratory representative; the laboratory director (LD) failed to ensure the laboratory performed quality control (QC) procedures for acceptability specified by the laboratory for endocrinology testing on the TOSOH AiA-360 (Serial Number: 2A482812) for 12 of 42 dates reviewed in 2024 (See D5445- A). Similarly, the LD failed to ensure the laboratory followed QC procedures for acceptable standard deviations ranges specified by the laboratory for endocrinology testing on the TOSOH AiA-360 for three of three "AIA-System Control Data" monthly QC charts reviewed in 2025, affecting 36 patients (See D5445-B). Likewise, the LD failed to ensure the laboratory followed QC procedures specified by the laboratory for two of two control lot change-over reviewed for endocrinology testing on the TOSOH AiA-360 (See D5445- C). The LD also failed to ensure the laboratory met the criteria for acceptability of quality control (QC) results prior to reporting patient test results as required per 493.1256 for 12 of 42 patient testing dates reviewed in the months of May and September of 2024 for endocrine testing using TOSOH AiA-360, affecting 19 patient results (See D5481).

D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) (b)(9) Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's CMS-209, policies and procedures, laboratory records and interview with the laboratory representative (LR); the technical consultant (TC) failed to evaluate and document the performance of one of two new testing personnel (TP) at least semiannually during the first year the TP tested patient specimens in the subspecialty of endocrinology from their date of hire (DoH) through the date of survey, 01/06/2026. Findings include: 1. Review of CMS-209 identified two new TP, (TP#1 and TP #2). 2. Review of laboratory policies and procedures revealed the procedure titled "Quality management Plan", under "QSE 2: Personnel", "4. Assessments" which stated, " ... an individual's competence is assessed at the following times: [point 2] Every 6 months during the first year of employment and once a year throughout employment". 3. Review of Pinnacle Fertility Job Summary for TP#2 indicated a DoH of 10/01/2024. 4. Review of testing personnel competency records indicated one of one competency assessment for TP #2 which was documented on 09/10/2024. 5. Interview with the laboratory representative, on survey date 01/06/2026 at 12:20 pm confirmed the TC failed to evaluate and document the performance of one of two new TP at least semiannually during the first year the TP tested patient specimens in the subspecialty of endocrinology from their DoH through the date of survey, 01/06/2026.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) (b)(9) Thereafter, evaluations must be performed at least annually This STANDARD is not met as evidenced by: Based on review of the laboratory's CMS-209, policies and procedures, laboratory records and interview with the laboratory representative (LR); the technical consultant (TC) failed to evaluate and document the performance of one of two testing personnel (TP) annually after the first year the TP tested patient specimens in the subspecialty of endocrinology in 2025. Findings Include: 1. Review of CMS-209 identified two TP, (TP#1 and TP #2). 2. Review of laboratory policies and procedures revealed the procedure titled "Quality management Plan", under "QSE 2: Personnel", "4. Assessments" which stated, " ... an individual's competence is assessed at the following times: [point 2] Every 6 months during the first year of employment and once a year throughout employment". 3. Review of testing personnel competency records found no competency assessment for TP #2 in 2025 performed by the TC. 4. Interview with laboratory representative, on survey date 01/06/2026 at 12:20 pm confirmed the TC failed to evaluate and document the competency of one of two TP annually in the subspecialty of endocrinology in 2025.