Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	32D1025903	03/23/2018
Name of Provider or Supplier	**Street Address, City, State**	
San Juan Oncology Associates	2325 E 30th St, Farmington, NM	

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 representative of the New Mexico State Agency completed a validation survey on 03/22/2018. Based on survey findings, the facility was not in compliance with 42 CFR 493, Laboratory Requirements. The laboratory was out of compliance with the following conditions: 42 CFR Part 493.1405 Laboratory Director, moderate complexity 42 CFR Part 493.1409 Technical Consultant Findings were discussed with the laboratory director and laboratory supervisor during the exit conference on 3/22 /18 at 4:30 pm.
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 the review of 2016-2017 proficiency test records, corrective action documentation and interview with the laboratory supervisor, the laboratory failed to identify the cause of the hematology failure for the 2nd event of 2017. Findings are: 1. Review of the overall proficiency scores for the 2nd event of 2017 indicated the laboratory received a score of 80% for Erythrocyte Count, Hematocrit, Hemoglobin, Leukocyte count, Basophils, Lymphocytes, and Monocytes. 2. Review of the data submitted to the proficiency agency indicated that the testing person could have run the same same sample (06) two times, once as 06 and the second as 07. 3. Review of the corrective action documentation indicated that the laboratory thought the failure was due to a poor calibration. The laboratory did not investigate the possibility that the samples were mixed up. 4. During interview with the laboratory supervisor on 3/21 /18 at 11:23 am, she stated that she had not reviewed the results or the corrective action documentation.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE

	CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on the review of 2016 proficiency testing records, quality assurance records and interview with laboratory staff, the laboratory failed to obtain training and/or technical assistance for the CA27.29 proficiency testing failures for the 1st and 2nd events of 2016. Findings are: 1. Review of the proficiency testing records revealed the laboratory received a score of 50% for the 1st and 2nd events of 2016 for the analyte CA27.29. 2. Review of the Checklist for Corrective Actions indicated the following: a. On 7/12/16, the laboratory concluded that "there may have been a small bubble or too much dilution used for testing" for the 1st event of 2016." There was no documentation indicating the laboratory had repeated the testing to support this conclusion. b. On 8/25/16, the laboratory was unable to determine the cause of the failure. The laboratory repeated all samples and the results were acceptable. 3. During interview on 3/21/18 at 11:12 am, the laboratory supervisor stated that she had contacted the accrediting agency about the failure but the agency did not request any documentation of corrective actions because CA27.29 was a non-regulated analyte. The laboratory supervisor also stated that the laboratory did not contact the proficiency agency or the TOSOH manufacturer for assistance.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: A. Based on the review of validation studies, manufacturer's instructions. laboratory policy, and interview with the laboratory supervisor, the laboratory failed to perform inter-assay precision studies for assays performed on the TOSOH AIA 360 Immunoassay analyzer and the ACE Axel Chemistry analyzer. This deficient practice could result in the laboratory's failure to identify potential error or bias when compared to the manufacturer's assay performance. Findings are: 1. Review of the manufacturer's instructions for the CA27.29 tumor marker assay (performed on the TOSOH AIA 360) indicated the following: a. Intra-assay precision statistics Control L; mean = 41.3 U/mL, 0.9 standard deviation (SD) and 2.2% Coefficient of Variation (CV) for 10 replicates. Control H; mean = 300.9 U/mL, 4.1 SD and 1.4% CV for 10 replicates. b. Inter-assay precision statistics Control L; mean = 40.4, 0.9 SD and 2.2% CV for 21 replicates. Control H; mean = 301.0 6.5 SD and 2.2% CV for 21 replicates. c. Review of the validation studies dated 04/28/10 for the CA27.29 revealed no documentation of inter-assay precision studies. 2. Review of the manufacturer's performance characteristics for the ACE Axel assays indicated the following: a. ALT (Alanine Aminotransferase) assay Intra-assay precision statistics, 21 days Sample 1; mean = 30 U/L, 2.1 SD, 6.9 % CV Sample 2; mean = 365 U/L, 5.7 SD, 2.1 % CV

	Sample 3; mean = 389 U/L, 4.5 SD, 1.1% CV Sample 4; mean = 55 U/L, 1.3 SD, 2.4% CV b. Alkaline Phosphatase assay Intra-assay precision statistics, 20 days Sample 1; mean = 50 U/L, 2.2 SD, 4.4 % CV Sample 2; mean = 690 U/L, 19.9 SD, 2.9 % CV Sample 3; mean = 1021 U/L, 28.3 SD, 2.8 % CV Sample 4; mean = 61 U /L, 2.9 SD, 4.7% CV c. Aspartate Aminotransferase assay Intra-assay precision statistics, 20 days Sample 1; mean = 24 U/L, 2.0 SD, 8.5 % CV Sample 2; mean = 220 U/L, 6.0 SD, 2.7 % CV Sample 3; mean = 398 U/L, 5.7 SD, 1.4 % CV Sample 4; mean = 115 U/L, 2.3 SD, 2.0% CV d. Review of the validation studies dated March 2016 for the ACE Axel revealed no documentation of inter-assay precision studies. 3. Review of the laboratory policy "Evaluation of Automated New Test Methods" indicated the laboratory should perform inter-assay precision studies. 4. During interview on 3/22/2018 at 2:30 pm, the laboratory supervisor stated she did not know if the inter-assay precision studies were performed for the TOSOH because she was not employed by the laboratory at the time. She also confirmed that intra-assay precision studies were not performed for the ACE Axel. B. Based on the review of validation studies, manufacturer's instructions, laboratory policy and interviews with laboratory staff, the laboratory failed to establish a CA27.29 assay reference range specific to the laboratory's patient population. Findings are: 1. Review of the manufacturer's instructions for the CA27.29 tumor marker assay indicated the following: a. "Because of differences in reagent specificity and assay methods, the concentration of CA27.29 in a given specimen may vary with devices from different manufacturers. Values obtained with different assay methods cannot be used interchangeably." b. "Each laboratory should determine a reference interval corresponding to the population being tested." c. In a healthy population, the reference interval for this assay was determined to be: Female Pre-Menopausal 28.6-44.3 U/mL Female Post Menopausal 38.9-43.4 U/mL Male 36.0-84.8 U/mL 2. Review of the laboratory's reference ranges dated 12/5/12 indicated a normal range 6.0 - 23.5 U/mL. There was no reference in the laboratory procedure manual or in the validation studies indicating the source of this range. 3. During interview on 3/21/18, the laboratory supervisor stated she did not know how the laboratory determined the reference interval or normal ranges because the assay was already in use when she was employed by the laboratory in 2012. 4. During the exit interview on 3/22/18 at 4:30 pm, the laboratory director could not recall how the laboratory determined the reference range for the CA27.29 assay. He further stated that the assay is used for monitoring treatment (not diagnosis) and the same patient could have widely differing results on different days. For this reason he was unsure of how to establish a reference range for the laboratory.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

	This STANDARD is not met as evidenced by: Based on the review of 2016-2017 quality assurance records, calibration records, manufacturer's instructions, instrument printouts, patient reports and interview with the laboratory supervisor, the laboratory failed to ensure that calibrations were performed for Ferritin, PSA (Prostate Specific Antigen), and TSH (Thyroid Stimulating Hormone) prior to patient testing. This failed practice could result in the laboratory reporting incorrect test values. Findings are: 1. Review of the manufacturer's instructions for Ferritin, PSA, and TSH indicated that calibration curves were stabile for 90 days. The manufacturer also indicated that the code "CV" would print on the instrument tape/printout for any assay with an expired calibration curve. The TOSOH AIA 600 chemistry analyzer was capable of storing 2 calibration curves for each assay and the laboratory would be able to recalculate any patient results using a different calibration curve. 2. Review of 2016 quality assurance records revealed the laboratory had failed to perform calibration of the Ferritin assay on 8/4 /16 after the calibration curve expired. The laboratory did not identify this failure until 8/23/16. The laboratory performed a calibration on 8/23/16, recalculated the patient results, and issued corrected reports for the patients affected. a.. Review of the instrument tapes for 08/09/19 revealed the Ferritin assay calibration curve was expired when the laboratory performed patient testing on 08/09/2016. 14 patients were tested, F1-F14. The laboratory's normal reference range was 25-280 ng/mL. F1 reported as 238; recalculated result = 255 F2 reported as 74; recalculated result = 79 F3 reported as 42; recalculated result = 45 F4 reported as 46; recalculated result = 50 F5 reported as 80; recalculated result = 85 F6 reported as 115; recalculated result = 122 F7 reported as 57; recalculated result = 61 F8 reported as 160; recalculated result = 171 F9 reported as 171; recalculated result = 183 F10 reported as 189; recalculated result = 201 F11 reported as 716; recalculated result = 763 F12 reported as 227.3; recalculated result = 213 F13 reported as 173; recalculated result = 162 F14 reported as 39; recalculated result = 37 3. Review of 2016-2017 calibration records revealed 2 additional incidents; PSA calibration expired on 7/11/16 and TSH calibration expired on 10/18/16. Review of the instrument tapes and patient reports revealed that the laboratory had not identified the failure to calibrate the PSA assay on 7/14/16. 3 patients, P1-P3 were tested on 7/14/16. Review of the patient reports confirmed the laboratory reported the results from the expired calibration curve. The laboratory reference range was 0.0-4.0 ng/mL. P1, collected on 7/13/16 at 12:27 pm, was reported as 29.0 ng/mL on 7/14/16 at 10:28 am. The instrument tape indicated a result of 29.02 on 7/14/16 at 09:19 am. P2, collected on 7/14/16 at 10:41 am, was reported as 6.6 ng/mL on 7/14/16 at 15:42 pm. The instrument tape indicated a result of 6.62 on 7/14/16 at 14:03 pm. P3, collected on 7/13/16 at 14:37 pm, was reported as 72.9 ng /mL on 7/14/16 at 10:28 am. The instrument tape indicated a result of 72.93 on 7/14 /16 at 9:20 am. 4. During interview on 3/21/18 at 11:00 am, the laboratory supervisor stated that she had found the Ferritin calibration failure on 8/23/16 when she returned to work after a 3 month absence. She confirmed that she did not identify the PSA calibration failure on 7/14/16.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.

	This STANDARD is not met as evidenced by: Based on the review of quality assessment records, quality control records, corrective action records, manufacturer instructions, proficiency testing records and interviews with laboratory staff, the laboratory failed to have an effective quality assessment policy. Findings are: 1. Review of the 2016 Quality Assurance Manual revealed no documentation in reference to CA27.29 proficiency testing failures for the 1st and 2nd event of 2016. a. During interview on 3/21/18 at 11:14 am, the laboratory supervisor stated that the laboratory does not usually review patient results as part of the proficiency testing corrective actions. b. Review of laboratory meeting agendas indicated no discussions regarding the proficiency testing failures. c. During interview on 3/21/18 at 11:16 am, the laboratory supervisor stated that proficiency testing scores are reviewed with the laboratory director at the time of reciept, not at the meetings. See D5221 2. Review of the 2017 Quality Assurance Manual revealed: a. There was no reference to the hematology proficiency testing failure in the July 2017 Monthly Summary. See D5211 b. The corrective action document dated 8/23/17 discussed calibration issues on the ABX Pentra hematology analyzer but did not indicate a resolution to the calibration failure. c. The corrective action document dated 9/27/17 referred to another calibration failure on 9/20/17 indicating issues with the platelet counts. There was no documentation of the resolution of the problem or that the laboratory assessed patient impact.
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 the review of validation studies, manufacturer's instructions, 2016-2017 proficiency test records, corrective action documentation, calibration records, instrument printouts, patient reports, quality assessment records, quality control records, and interviews with laboratory staff, the laboratory director failed to provide overall direction and management of the laboratory. Findings are: 1. The laboratory failed to perform inter-assay precision studies for assays performed on the TOSOH Immunoassay analyzer. See D6013 - 1 2. The laboratory failed to establish reference ranges for the CA27.29 assay specific to the laboratory's patient population See D6013 - 2 3. The laboratory failed to investigate the hematology failure for the 2nd event of 2017. See D6019 4 The laboratory failed to have an effective quality assessment policy. See D6021
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;

	This STANDARD is not met as evidenced by: Based on the review of validation studies, manufacturer's instructions, laboratory policy and interviews with laboratory staff, the laboratory director failed to ensure that all verification procedures were performed for each assay/test performed in the laboratory. Findings are: 1. The laboratory failed to perform inter-assay precision studies for analytes performed on the TOSOH AIA 360 Immunoassay analyzer and the ACE Axel Chemistry analyzer. See D5421-A 2. The laboratory failed to establish a CA27.29 assay reference range specific to the laboratory's patient population. See D5421-B
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on the review of 2016-2017 proficiency test records, corrective action documentation and interview with laboratory staff, the laboratory director failed to ensure an approved corrective action plan is followed for all proficiency testing failures. Findings are: 1. The laboratory failed to obtain training and/or technical assistance in 2016 for 2 consecutive proficiency failures for the CA27.29 assay. See D5221 2. The laboratory failed to identify the cause of the hematology failure for the 2nd event of 2017. See D5211
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on the review of quality assessment records, quality control records, corrective action records, manufacturer instructions, proficiency testing records and interviews with laboratory staff, the laboratory director failed ensure that an effective written quality assurance policy was followed by the laboratory. Findings are: The laboratory failed to have an effective quality assessment policy that included reviews of proficiency testing failures, calibration failures and other incidents in the monthly quality assurance reports. See D5793
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY

	CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on the review of validation studies, manufacturer's instructions, 2016-2017 proficiency test records, corrective action documentation, calibration records, instrument printouts, patient reports, quality assessment records, quality control records, CMS Form 209, and interviews with laboratory staff, the technical consultant failed to provide technical oversight of the laboratory. Findings are: 1. The laboratory failed to perform inter-assay precision studies for assays performed on the TOSOH Immunoassay analyzer. See D6040 - 1 2. The laboratory failed to establish reference ranges for the CA27.29 assay specific to the laboratory's patient population. See D6040 - 2 3. The technical consultant failed to review analyzer records including calibration and quality control as part of the competency evaluation of testing personnel. See D6033 4. According to the Personnel Report Form, CMS 209, the laboratory director also served as the technical consultant of the laboratory.
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on the review of validation studies, manufacturer's instructions, laboratory policy and interviews with laboratory staff, the technical consultant failed to ensure that all verification procedures were performed for each assay/test performed in the laboratory. Findings are: 1. The laboratory failed to perform inter-assay precision studies for analytes performed on the TOSOH AIA 360 Immunoassay analyzer and the ACE Axel Chemistry analyzer. See D5421-A 2. The laboratory failed to establish reference ranges for the CA27.29 assay specific to the laboratory's patient population. See D5421-B
D6049	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iii) The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. This STANDARD is not met as evidenced by: Based on the review of 2016-2017 quality assurance records, calibration records, manufacturer's instructions, instrument printouts, patient reports and interview with the laboratory supervisor, the technical consultant failed to review analyzer records including calibration and quality control as part of the competency evaluation of testing personnel. Findings are: The laboratory failed to ensure that calibrations were

	performed for Ferritin, PSA (Prostate Specific Antigen), and TSH (Thyroid Stimulating Hormone) prior to patient testing. See D5437