Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2004819	07/15/2021
Name of Provider or Supplier	**Street Address, City, State**	
Winke Orthopedic Pain Management Center	808 Eden Way North, Suite 102, Chesapeake, VA	

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	An announced CLIA validation survey was conducted at Winke Orthopedic Pain Management Center on July 15, 2021 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows and include the Conditions under 42 CFR part 493 CLIA Regulation: D5400 -42 CFR. 493.1250 Analytic Systems, D6076 -42 CFR. 493.1441 Laboratory Director.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on a review of policies and procedures, available proficiency testing (PT) records, test logs, and an interview, the laboratory failed to perform twice annual accuracy verification for fifty-five (55) of seventy-three (73) urine toxicology (non regulated) tests reported on the Sciex mass spectrometer (MS) analyzer per their policy for the twenty-four (24) months reviewed (July 2019 to up to date of the inspection on July 15, 2021). Findings include: 1. Review of the laboratory's Quality Assurance policies revealed a PT policy (titled: Split Sample Testing) that stated, "The lab will externally verify the accuracy of all non regulated non waived tests not enrolled in PT using a minimum of five specimens twice per year". 2. Review of the laboratory's College of American Pathologists (CAP) UT Urine Toxicology PT documentation for calendar year 2019 to the date of survey on 7/15/21, a total of four (4) events, revealed participation for eighteen analytes included on the laboratory's screening panel. The PT events did not include all analytes assayed by the laboratory included on their confirmation panel. 3. Review of the patient test logs revealed the confirmation panel included the following additional 55 analytes: 6-Acetylmorphine, 7-Aminoclonazepam, Hydroxyalprazolam, Amphetamine, Alprozolam, Amitiptyline,

	Benzoylecgonine, Buproprion, Butalbital, Carisoprodol, Clonazepam, Codeine, Clycobenzaprine, Desipramine, Diazepam, Doxepin, Dulozetine, Ethyl-Sulfate, Meprobamate, Mitragynine, EDDP, Fentanyl, Fluoxetine, Gabpentin, Hydrocodone, Hydromorphone, Ketamine, Lorazapam, MDMA, Methamphetamine, Meperidine, Morphine, Nortriptyline, Naloxine, Naltrexone, Norbuprenorphine, Nordiazepam, Norfentanyl, N-desmethyl-Tapentadol, Norhydrocodone, Normeperidine, Noroxycodone, Oxymorphone, Oxaepam, PCP, Pregabalin, Phenobarbitol, Ritalinic Acid, Secobaritol, Sertraline, Tapentadol, Temazepam, Tramadol, Venlafaxine, and Zolpidem. The inspector requested documentation of twice annual PT or accuracy verification for the additional drug confirmation panel test analytes outlined above in calendar years 2019, 2020, and up to the date of the survey. The Technical Supervisor (TS) provided one split panel accuracy verification report for all analytes (performed on 3/17/20, reviewed by the LD 6/25/21). No additional accuracy verification was available for review. 4. An exit interview with the TS on 7/15/21 at approximately 2 PM confirmed the above findings.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on a review of policy/procedure manual, CLIA Centers for Medicare and Medicaid Services Survey (CMS 116) form, instrument maintenance logs, manufacturer's operations manual, a tour, interviews, and lack of documentation , the laboratory failed to: 1. ensure their procedure for mass spectrometer (MS) urine toxicology screening/confirmation panels included an assessment for interfering substances, criteria for the evaluation of potential carryover, or quality control procedures outlining cut off values for positive and negative results for each of seventy-three (73) drug analytes analyzed/reported on the Sciex MS instrument; 2. document retired policies and procedures noted on the date of the survey July 15, 2021; 3. document performance of required MS analyzer maintenance protocols for seventeen (17) of eighteen (18) months reviewed (January 2020 to July 15, 2021); 4. document function checks of revolutions per minute (RPM) verification for the VWR centrifuge twice annually per their policy in calendar years 2019 and 2020. See D5403, D5409, D5429, D5435.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other

	materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on the review of the policy/procedure manual and an interview, the laboratory's procedure for mass spectrometer (MS) urine toxicology screening/confirmation panels did not include an assessment for interfering substances, criteria for the evaluation of potential carryover, or quality control (QC) procedures outlining cut off values for positive and negative results for each of seventy-three (73) drug analytes analyzed /reported on the Sciex MS instrument. Findings include: 1. Review of the available Sciex MS urine toxicology procedures for each of the 73 analytes revealed no evaluation, overview, or documentation of: Requirements for specimen acceptability, storage temperature, rejection due to age of specimen; Limitations for interfering substances; QC procedures that outline cut off values for positive and negative results; Calibration procedures; and Criteria for evaluation of potential carryover from a preceding elevated (high concentration) sample to the following sample in each analytical batch analysis. The inspector requested to review the additional procedure requirements outlined above. No documentation was available. The technical supervisor (TS) stated on 7/15/21 at approximately 11:00 AM: "We are in process of updating our policies and procedures". 2. An exit interview with the TS on 7/15/21 at approximately 2 PM confirmed the above findings.
D5409	PROCEDURE MANUAL CFR(s): 493.1251(e) The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2). This STANDARD is not met as evidenced by: Based on review of the laboratory's CLIA Centers for Medicare and Medicaid Services Survey (CMS 116) form, a tour, review of policies and procedures, and an interview, the laboratory director (LD) failed to document retired policies and procedures noted on the date of the survey July 15, 2021. Findings include: 1. Review of the CMS 116 form revealed that the LD reported that the high complexity laboratory performed high complexity toxicology panels analyzed by mass spectrometer analyzer. 2. During a tour of the laboratory, the inspector noted that one (1) Sciex 4500MD Mass Spectrometer (Serial Number 20161712) in use. 3. Review of the laboratory's procedures revealed protocols and procedures related to a Medica Easy RA chemistry analyzer no longer located in the laboratory. The inspector inquired regarding a discontinuation date for retired procedures (signed and approved by a previous LD). The technical supervisor (TS) stated on 7/15/21 at approximately

	11:00 AM: "We are in process of updating our policies and procedures". 4. An exit interview with the TS on 7/15/21 at approximately 2 PM confirmed the above findings.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a tour, review of instrument maintenance logs, manufacturer's operations manual, interviews, and lack of documentation, the laboratory failed to document performance of required analyzer maintenance protocols for seventeen (17) of eighteen (18) months reviewed (January 2020 to July 15, 2021) Findings include: 1. During the onsite validation survey tour on 7/15/21 at approximately 10:00 AM, the inspector requested to review the ABSciex 4600 (Serial Number SN 20161712) analyzer maintenance logs for calendar year 2020 and up to year to date. The testing personnel provided a log for June 2021 with one date recorded (06/30/21) and a log for July 2021 with ongoing maintenance recorded. No additional maintenance logs were available for review. The inspector inquired regarding the 17 month lack of documentation. The testing personnel stated: "We started with this new analyzer in January 2020 and do the maintenance as required but did not record it on a log. We started a log this month". 2. Review of ABSciex mass spectrometer operations manual revealed manufacturer's start up/shut down and maintenance instructions (under Operations and Service/Maintenance chapters) related to the protocols outlined on the maintenance log as: Daily: Check Adequate Mobile Phases, Needle Rinse, Adequate Waste Volume/Change, Check Pressure of Pump A and B, N2 Generator Pressure Check, Note Number of Injections; PRN: Change Guard (at 400 injections), change Column (at 3000 injections); Weekly: Clean Curtain Plates; Annual and as Needed: Service PM. 3. The inspector inquired of the laboratory's policy related to the frequency of the maintenance. The technical supervisor (TS) stated at approximately 11:00 AM: "The maintenance was performed per the manufacturer's instructions but not documented until recently when a log was instituted". 4. In an exit interview with the TS on 7/15/21 at approximately 2 PM the above findings were confirmed.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on a tour, review of procedures, maintenance logs, lack of documentation, and

	an interview, the laboratory failed to document function checks of revolutions per minute (RPM) verification for the VWR centrifuge twice annually per their policy in calendar years 2019 and 2020. Findings include: 1. During a tour of the laboratory on 07/15/21 at approximately 10:00 AM the inspector noted one (1) VWR centrifuge (Serial Number 00383) in use for toxicology specimen processing. 2. Review of the laboratory's procedures revealed the two following protocols: Centrifuge Operation and Maintenance - that stated "RPM calibration will be performed every six months using a digital tachometer"; and Qualitative Determination of Drugs via LCMS/MS Sample Prep - that stated on step 11: "Centrifuge all vials for 10 minutes at approximately 13,000 RPM." 3. Review of the laboratory's 2019 and 2020 maintenance documentation revealed no records of verifications of the VWR centrifuge for 13,000 RPM as outlined above. The inspector requested to review the twice annual centrifugation function checks for the timeframe of January 2019 to July 2021. The technical supervisor (TS) provided one maintenance report dated 7/14/21 with the RPM verified at 13,024. No other documentation was available for review. 4. An exit interview with the TS on 7/15/21 at approximately 2 PM confirmed the above findings.
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 a review of the laboratory's proficiency testing (PT) results, PT policy, performance verification records for the laboratory's Sciex mass spectrometer analyzer installed in January 2020, CLIA Laboratory Personnel Report (CMS 209) Form, available testing personnel (TP) files, lack of documentation, and interviews, the laboratory director failed to: 1. document PT performance review per the laboratory's procedure guideline for urine toxicology PT for (2) of 2 events in calendar year 2020; 2. evaluate and verify the performance analytical sensitivity and assess matrix effects for the urine toxicology panel testing (screening and confirmation) prior to reporting three hundred fifty-five thousand, five hundred eighty-three (355,583) patient results from January 2020 and up to the date of the survey on July 15, 2021; 3. ensure competency assessments were performed for two (2) of 2 TP and for one (1) of 1 Technical Supervisor (TS) / General Supervisor (GS) in calendar year 2020 and up to the date of the survey on July 15, 2021. See D6091, D6095, D6102.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on a review of the laboratory's proficiency testing (PT) results, PT policy, and an interview, the laboratory director (LD) failed to document performance review per

	the laboratory's procedure guideline for urine toxicology PT for (2) of 2 events in calendar year 2020. Findings include: 1. Review of the laboratory's College of American Pathologists (CAP) Urine Toxicology PT records revealed that the LD reviewed events UT-B 2020 and UT C 2020 on 6/25/21. The inspector inquired regarding why the review was dated a year late. The technical supervisor (TS) stated "We are working to improve recording and documentation of the oversight of the proficiency results". 2. Review of the laboratory's PT policy revealed guideline: "Once results are received, they will be promptly evaluated Laboratory Director or qualified designee, the review will be documented and results will be shared with the testing personnel". 3. An exit interview with the TS on 7/15/21 at approximately 2 PM confirmed the above findings.
D6095	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6) The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system. This STANDARD is not met as evidenced by: Based on a review of all available performance verification records for the laboratory's Sciex mass spectrometer analyzer installed in January 2020, test logs, and an interview, the laboratory director (LD) failed to evaluate and verify the performance analytical sensitivity and assess matrix effects for the urine toxicology panel testing (screening and confirmation) prior to reporting three hundred fifty-five thousand, five hundred eighty-three (355,583) patient results from January 2020 and up to the date of the survey on July 15, 2021. Findings include: 1. Review of analyzer performance verification documentation revealed no evaluation or verification by the LD for urine toxicology panel analytes' established sensitivity or an assessment of matrix effects for the ABSciex 4600 (Serial Number SN 20161712). The inspector requested to review documentation that the laboratory director verified sensitivity and matrix effects for the screening/confirmation analytes in the toxicology panels prior to patient testing. No documentation was available for review. 2. Review of the patient logs revealed that the lab had reported 355,583 patient toxicology analyte results up to the date of the survey on 7/15/21. The technical supervisor (TS) stated on 7/15/21 at approximately 12:00 noon that the additional validation studies were in progress. 3. An exit interview with the TS on 7/15/21 at approximately 2 PM confirmed the above findings.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on a review of the CLIA Laboratory Personnel Report (CMS 209) Form, available testing personnel (TP) files, lack of documentation, and an interview, the laboratory director (LD) failed to ensure competency assessments were performed for

	two (2) of 2 TP and for one (1) of 1 Technical Supervisor (TS) / General Supervisor (GS) in calendar year 2020 and up to the date of the survey on July 15, 2021. Findings include: 1. Review of the CMS 209 form revealed that the LD identified TP A and TP B responsible for the high complexity toxicology chemistry testing. The LD noted on the CMS 209 that TP B also served as TS and GS 2. Review of the laboratory personnel files revealed: TP A - an initial training record completed February 2020 and an annual toxicology competency evaluation signed by the TS in March 2021. TP B- no competency assessments were available for review for role of TP, GS or TS. The inspector requested to review a semiannual competency assessment for TP A in 2020 and competency assessments for TP B in the assigned roles for 2019 and 2020. No record was available for review 3. In an interview with the TS on 7/15/21 at approximately 1 PM the above findings were confirmed.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on a review of Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory personnel files, lack of documentation, and an interview, the technical supervisor (TS) failed to perform a semiannual toxicology competency evaluation for one (1) of one (1) testing personnel in calendar year 2020. Findings include: 1. Review of the CMS 209 form revealed that the laboratory director identified one TS and two testing personnel (TP) responsible for high complexity toxicology chemistry testing. 2. Review of the laboratory personnel files revealed an initial training record for TP A completed February 2020 and an annual toxicology competency evaluation signed by the TS in March 2021. The inspector requested to review a semiannual competency assessment for TP A in 2020. No record was available for review. (See Personnel Code Sheet.) 3. In an interview with the TS on 7/15/21 at approximately 1 PM the above findings were confirmed.