Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	43D1034766	05/02/2018
Name of Provider or Supplier	**Street Address, City, State**	
Cnos Pc	705 Sioux Point Road Suite 100, Dakota Dunes, SD	

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 for compliance with 42 CFR Part 493, Requirements for Laboratories, was conducted on 5/2/18. The Midlands Clinic PC laboratory was found not in compliance with the following requirements: D5217 and D5471.
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 review of test accuracy documentation, form CMS209, and policy review, and laboratory director interview, the laboratory failed to verify and document the accuracy of the test methods used for patient tissue slides and potassium hydroxide (KOH) tests twice a year for 21 of 21 months reviewed (July 2016 through April 2018). Findings include: 1. Review of the laboratory's documentation of the accuracy of patient tissue slide testing revealed there had been no documentation the accuracy of patient tissue slide testing performance had been verified twice a year for the time frame above. Review of the Peer to Peer Review policy, signed 6/13/16, revealed "twice yearly slide review sampling five to 10 percent of slides will be reviewed." Review of the Mohs Quality Assurance Log revealed twenty cases from 2016 and nineteen cases from 2017 had been reviewed on 9/11/17 and found acceptable. No other documentation of a verification of accuracy for 2016 or 2017 had been available. Interview on 5/2/18 at 1:35 p.m. with the lab director revealed: *She and another pathologist looked at several cases a year and discussed them together. *They had planned to do the reviews in the spring and fall, and they had reviewed slides last fall. 2. Review of the laboratory's documentation of the accuracy of the KOH test method revealed there had been no documentation the accuracy of the test method had been verified twice a year for the time frame above. Review of the current staff responsibility policy (2006 revision) revealed the technical consultant had been

	responsible for ensuring participation in a proficiency testing program. Review of the CMS 209 form revealed the laboratory director also served as the technical supervisor (consultant). Interview on 5/2/18 at 1:50 p.m. with the lab director revealed: *She was unaware of the necessity of verifying the accuracy twice yearly of the KOH testing method.
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation of the potassium hydroxide (KOH) reagent, review of the annual test volume form, and laboratory director interview, the laboratory failed to check each lot number or shipment of the KOH reagent for its positive reactivity prior to patient testing during 2016, 2017, or 2018. Findings include: 1. Review of available records revealed no documentation of quality control (QC) having been done on the KOH reagent in 2016, 2017, or 2018. In addition there was no documentation when lot numbers changed, or a new shipment of the same or different lot number was received. Observation of the bottle of 20% KOH reagent (lot # K179S5, expiration date 9/30/20) at 1:50 p.m. on 5/2/18 revealed it had not been dated as to when it was received. The bottle appeared to be full. No QC documentation had been available. Review of the annual testing volume form indicated 228 KOH patient tests had been performed duing 2017. Interview at the above time with the laboratory director revealed she was unaware QC was required of a new lot number or shipment before use on patient samples.