Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1106366	01/12/2023
Name of Provider or Supplier	**Street Address, City, State**	
Woodlands Skin Surgery, Pa,The	13325 Hargrave Road Suite 130, Houston, TX	

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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found in compliance with applicable CLIA Conditions, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the CMS Southern Operations Branch-Dallas for referral to the Office of Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D3013	FACILITIES CFR(s): 493.1101(e) Records and, as applicable, slides, blocks, and tissues must be maintained and stored under conditions that ensure proper preservation. This STANDARD is not met as evidenced by: Based on surveyor's observations on 01/12/2023 at 1020 hours in the storage room, review of laboratory's policies and procedures, and staff interview, it was determined the laboratory failed to define and monitor storage conditions for proper preservation of processed histopathology slides. Findings included: 1. Surveyor's observations on 01/12/2023 at 1020 hours revealed previously processed histopathology slides were stored in a storage room which was not monitored for either temperature or humidity to ensure their proper preservation. 2. Review of laboratory's policies and procedures revealed the laboratory did not have protocols in place defining storage conditions to ensure proper preservation of processed slides. 3. In an interview on 01/12/2023 at 1025 hours in the break room, the Lab Tech (as identified on the facility's Entrance Conference documentation), after review of the data, confirmed the findings.

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 review of laboratory's policies and procedures, review of the laboratory's twice annual accuracy verification/proficiency testing (PT) records for 2021 and 2022, and staff interview, it was determined the laboratory failed to document evaluation /comparison of results to initial diagnosis of 24 of 24 reviewed PT results. Findings included: 1. Review of laboratory's policy "Quality Assurance Procedure" revealed: "Three separate Mohs surgery case slides are randomly selected per laboratory location and sent out twice a year for quality control. If multiple physicians practice at a given location, then three case slides will be selected for each practicing physician and sent for quality control." And, "A log is maintained for the sending of the case slides and results are obtained. A comparison of results is performed..." 2. Review of the laboratory's twice annual accuracy verification /PT records for 2021 and 2022 revealed the laboratory failed to document evaluation/comparison of the following 24 of 24 reviewed PT sample results to verify whether the diagnosis was found to match initial diagnosis: Event date: 05/12/2021 Slide Number: CN21-013 Slide Number: CN21-023 Slide Number: CN21-130 There was no documented comparison of results to verify if diagnosis was found to match the initial case. Event date: 05/19/2021 Slide Number: S21-012 Slide Number: S21-062 Slide Number: S21-095 There was no documented comparison of results to verify if diagnosis was found to match the initial case. Event date: 01/12/2022 Slide Number: S21-175 Slide Number: S21-192 Slide Number: S21-244 There was no documented comparison of results to verify if diagnosis was found to match the initial case. Event date: 01/13/2022 Slide Number: CN21-280 Slide Number: CN21-298 Slide Number: CN21-488 There was no documented comparison of results to verify if diagnosis was found to match the initial case. Event date: 04/28/2022 Slide Number: CN22-117 Slide Number: CN22-148 Slide Number: CN22-150 There was no documented comparison of results to verify if diagnosis was found to match the initial case. Event date: 08/19/2022 Slide Number: S22-062 Slide Number: S22-063 Slide Number: S22-098 There was no documented comparison of results to verify if diagnosis was found to match the initial case. Event date: 01/04/2023 Slide Number: S22-215 Slide Number: S22-135 Slide Number: S22-136 There was no documented comparison of results to verify if diagnosis was found to match the initial case. Event date: 01/10/2023 Slide Number: CN22-550 Slide Number: CN22-564 Slide Number: CN22-643 There was no documented comparison of results to verify if diagnosis was found to match the initial case. 3. In an interview on 01/12/2023 at 1015 hours in the break room, the Lab Tech (as identified on the facility's Entrance Conference documentation), after review of the data, confirmed the findings.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

	This STANDARD is not met as evidenced by: Based on surveyor's observations, review of laboratory's policies and procedures, review of laboratory's equipment maintenance records for 2021 and 2022, and staff interview, it was determined the laboratory failed to follow its own policy for documentation of annual periodic maintenance for 3 of 3 instruments used by the laboratory. Findings included: 1. Surveyor's observations on 01/12/2023 at 1020 hours in the laboratory revealed the laboratory used the following equipment: Shandon Linistain stainer (BIOMED number 491125) Avantik Cryostat (BIOMED number 392367) Microscope (BIOMED number 491126) 2. Review of laboratory's policy "Quality Assurance Procedure" revealed: "Periodic maintenance once a year is done on the cryostat, stainer, and microscopes." 3. Review of laboratory's equipment maintenance records for 2021 and 2022 revealed no annual periodic maintenance documented for 2021 and 2022. The last annual periodic maintenance was documented in 2018. 4. The laboratory was asked to provide documentation of the annual periodic maintenance for the above equipment and no such documentation was available for review. 5. In an interview on 01/12/2023 at 1025 hours in the break room, the Lab Tech (as identified on the facility's Entrance Conference documentation), stated that periodic maintenance was performed once yearly, but could not locate the documentation. This confirmed the findings.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the laboratory's Cryostat temperature records for January to December of 2022, review of laboratory's corrective action records, review of laboratory's policies and procedures and staff interview, it was determined the laboratory failed to document corrective action for 9 of 9 days laboratory's Cryostat's temperature was out of laboratory defined range. Findings included: 1. Review of the laboratory's Cryostat temperature records for January to December of 2022 revealed: "The optimal cryostat cutting range in this lab is between -25 and -31 degrees Celcius (sic)." 2. Further review of the laboratory's Cryostat temperature records for January to December of 2022 revealed the following days the temperature was documented outside of laboratory defined range: Date: Temperature: 03/31/2022 -32C 08/31/2022 32C (+32C) 09/08/2022 -32C 09/15/2022 32C (+32C) 10/13/2022 -32C 11/03/2022 -32C 11/10/2022 -32C 12/01/2022 -32C 12/08/2022 -32C 3. Review of laboratory's corrective action documents revealed no documentation of corrective action for the above out of laboratory defined range temperatures. 4. Review of laboratory's policies and procedures revealed there was no policy in place regarding documentation of corrective actions for out-of-range operational parameters for the Cryostat. 5. In an

	interview on 01/12/2023 at 1015 hours in the break room, the Lab Tech (as identified on the facility's Entrance Conference documentation), after review of the data, confirmed the findings.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of laboratory's quality assurance (QA) records for 2021 and 2022, review of equipment maintenance and temperature records for 2021 and 2022, surveyor's observations and staff interview, it was determined the laboratory's QA failed to identify and correct issues with equipment periodic annual maintenance and out of range cryostat temperature corrective action. Refer to D5401 and D5781.
D6096	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7) The laboratory director must ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, review of laboratory's Cryostat temperature logs and staff interview, it was determined the Laboratory Director failed to ensure remedial actions were documented for out of laboratory defined range Cryostat temperatures. Refer to D5781.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form 209, review of laboratory's policies and procedures and staff interview, it was determined the Laboratory Director failed to specify in writing the responsibilities and duties of Testing Personnel, 1 of 5 position types within the laboratory. Findings included: 1. Review of the laboratory's submitted Form 209 revealed the laboratory employed two Testing Personnel. 2. Review of laboratory's policies and procedures revealed there was no policy in place

	specifying in writing the responsibilities and duties (job description) of Testing Personnel. 3. In an interview on 01/12/2023 at 1015 hours in the break room, the Lab Tech (as identified on the facility's Entrance Conference documentation), after review of the data, confirmed the findings.