ION LABS	Standard Operating Procedure **ATP Testing for Production Equipment**	**SOP Number** **D-116**	**Revision** **0**
		Effective Date 04/12/22	**Page** **Page 1 of 6**

Written by/ Date	**Reviewed by/ Date**	**Approved by/ Date**
03/16/22	03/14/22	05-16-22
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1.0 Purpose

The purpose of this procedure is to define the use of the surface ATP cleanliness test using Neogen AccuPoint Advanced ATP Surface Test to demonstrate production equipment is sanitized properly. The system is designed to detect adenosine triphosphate (ATP) at set thresholds and to report the measurement in relative light units (RLUs). ATP is a chemical compound found in all living cells, including bacteria, food debris, yeast and mold. After swabbing, the swab is inserted into a device called a luminometer, which reads the amount of light produced by the sample. The light produced is proportional to the amount of ATP in it: the more bacteria or product residue on the surface, the more ATP; the more ATP, the more light produced.

2.0 Scope

This procedure describes the use of surface test methods in the verification of cleaning instructions to ensure each piece of production equipment is clean. These ATP test methods are not valid for the testing of cleaning fluids used in removing organics from production surfaces. This procedure is specific to the testing of dry production equipment surfaces. A general ATP test is the primary screen for detecting organic residues remaining on surfaces after cleaning of production equipment surfaces.

3.0 Responsibility

3.1 It is the responsibility of QC Laboratory Management and/or designee to implement and maintain this procedure and to ensure that the procedure is being followed.

3.2 It is the responsibility of Quality Unit to execute monitoring activities.

3.3 It is the responsibility of Production Personnel to clean production equipment as per SOP B-111 Cleaning of Manufacturing/Production Areas and Equipment and other applicable cleaning procedures.

3.4 It is the responsibility of Quality Management to review and approve all validation and test documentation and to notify production management when revalidation is required.

4.0 Definitions

4.1 **DC** – Document Control

4.2 **QC** – Quality Control

4.3 **AD** – Analytical Development

5.0 References

5.1 B-111, SOP, Cleaning of Manufacturing/Production Areas and Equipment

5.2 C-502, SOP, Record Storage, Retention, and Destruction

5.3 D-116-F1, Form, ATP Swab Test Ticket

6.0 Equipment/Materials

6.1 Surface ATP Test Kit

6.1.1 Product

6.1.1.1 AccuPoint Advanced ATP Surface Sampler, Cat #9405

6.1.1.2 AccuPoint Field Cleaning Kit, Cat #9612

6.1.1.3 Neogen AccuPoint Advanced ATP Sanitation Monitoring System, Cat #9903

6.1.2 Equipment

6.1.2.1 Neogen ATP Test Method

6.1.3 Specifications (Neogen)

6.1.3.1 Test Time: 10 seconds

6.1.3.2 Storage: 2-8°C

6.1.3.3 Samplers must be warmed to room temperature prior to use for at least one hour.

6.1.3.4 Samplers may be stored for up to two weeks outside of the refrigerator.

7.0 Procedure

Note: All employees performing ATP tests must be properly garbed (hair net, gloves, lab coat or frock, shoe covers, etc.)

7.1 Quality will conduct ATP Swab testing after a successful visual inspection as indicated by SOP B-111.

7.1.1 Quality will swab up to five (5) areas from each defined equipment grouping (see attachment 1) for the presence of ATP as defined in section 7.2. Some equipment groupings may not contain five (5) different areas for swabbing. In these cases, swabbing of each product contact area should be performed.

7.1.2 Quality will prioritize hard to clean areas or any area in which accumulation of product may occur during the swabbing procedure.

7.2 ATP Swab Testing Procedure – Surface Sampling (ATP). The instructions below are generalized for the Neogen ATP Surface sampling test.

7.2.1 Remove sampler cartridges from refrigeration and warm to room temperature for at least one hour prior to use. Keep extra samplers in pouch, protected from light.

Note: Swabs may remain out of refrigeration for 2 weeks. When a new pack of samplers is removed from refrigeration, they will be marked with a "Use By" date to ensure that samplers are not used that have remained out of refrigeration past the two week time period.

7.2.2 Turn on the AccuPoint Advanced ATP Sanitation Monitoring System. Allow instrument warm up for 5-10 minutes before taking the first reading.

7.2.3 Check the display to make sure that the instrument is ready.

Note: If the instrument is not ready, there may be a used sampler cartridge inside. Press the eject button to discard the cartridge, close the sampler door, and turn the instrument off, then back on to clear the error.

7.2.4 Prepare to go to the first testing site.

7.2.5 Grasp a sampler by its handle and pull it out of the cartridge. To ensure accurate test results, do not touch the tip of the sampler, or let the tip touch any other surface prior to testing.

7.2.6 Swab the area of approximately 10cm x 10cm (if the equipment allows) for Organic Residuals. The surface should be swabbed firmly starting in one corner and forming a continuous line going back and forth across the square. Repeat the procedure with slightly less pressure starting at 90 degrees from first start point.

7.2.7 Reinsert the sampler into its cartridge and fully depress. Mix for 2 seconds in a side-to-side motion.

7.2.8 Press the EJECT button to open the top door on the instrument. Keep the unit upright while testing. Insert the sampler with its cartridge into the sampler compartment. The symbols are a green checkmark to indicate PASS, a yellow question mark to indicate a MARGINAL, and a red X to indicate a FAIL. Record the numeric RLU value and record "Pass" if the value is less than 300 and "Fail" if the value is equal to or greater than 300 RLU.

Note: The manufacturer recommends the limit of 300 RLU.

7.2.9 Document testing information and report the result on Form D-116-F1 ATP Swab Test Ticket if not using Redzone. SOP B-111 provides details for using Redzone for cleaning documentation.

7.2.10 Report testing results to the appropriate personnel.

7.2.11 Press the EJECT button and remove the sampler from the chamber. Samplers and their cartridges are non-toxic and may be disposed of without any special considerations.

7.2.12 Once all samples are finished for the day, turn the instrument off. Clean the outer surface of the instrument with mild detergent and a slightly moistened cloth. Turn the instrument upside down and use the AccuPoint Cleaning Kit Swab to clean the interior surface of the instrument.

8.0 Records

8.1 Redzone is the preferred method for documentation of ATP swab results. Use Form D-116-F1 ATP Swab Test Ticket if not using Redzone. Fill in information as follows:

8.1.1 Room#- Location of equipment at the time of testing

8.1.2 Test Date – The date the test was performed

8.1.3 Description of equipment swabbed

8.1.4 Equipment Group – The cleaning instruction that will be impacted if the cleaning validation passes or fails on any one or combination of machine tests (See Attachment 1).

8.1.5 Initial Test / Retest- Identify the iteration of test for release of equipment.

8.1.6 Major Clean Performed – Identify if a major clean was performed just prior to ATP testing

8.1.7 Results: The test passes if the green checkmark displays. The result fails if the red X displays. All marginal samples must be retested immediately and if still marginal the test fails.

8.1.8 Total Result – The combined result of all swab tests. If all tests are PASS, the survey passes. If one or more tests fail, the survey fails

8.1.9 Survey Failure – Operational Management must be notified immediately of the failure. The equipment must be re-cleaned and retested.

8.1.10 Repeat steps 7.2.1-7.2.12.

8.2 ATP Test Records are maintained by the Quality Group following SOP C-502 Record Storage, Retention, and Destruction.

9.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	10/05/21	New.	N/A	G. Shaw

10.0 Attachments

10.1 Attachment 1 – Major Equipment Grouping

Attachment 1 – Major Equipment Grouping

Production Equipment Grouping List	
Blending	Tableting
Compression	Encapsulation
Packaging	Coating
Gummy	Liquid

ION LABS	ATP Swab Test Ticket		
	Form: D-116-F1	CCR No. N/A	Revision: 0

Room#: _____ **Test Date:** _____

Sampler Lot#: _____ **Sampler Expiration Date:** _____

Equipment Group: _____ □ **Initial Test** □ **Retest (1 2 3 __)**

Type Test: ***Surface ATP*** **Major Clean Performed (Y/N):** _____

Previous Batch #: _____ **Formula#:** _____

Swab 01 **Value on screen**

Equipment Description: Result : _____ (circle one): Pass Fail

Swab 02

Equipment Description: Result : _____ (circle one): Pass Fail

Swab 03 □ **N/A**

Equipment Description: Result : _____ (circle one): Pass Fail

Swab 04 □ **N/A**

Equipment Description: Result : _____ (circle one): Pass Fail

Swab 05 □ **N/A**

Equipment Description: Result : _____ (circle one): Pass Fail

Final Result (Circle One): Pass Fail

Test Performed By/Date: _____ Reviewed By/Date: _____