



BODYBIO INC.

SOP# 02-006.2	Standard Operating Procedure	Written/Revised By:  12/20/21
Effective Date: JAN 06 2022	Interim Cleaning Verification Check for Non- Water Based Applications	Approved By:  12/20/21
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1. Purpose

- 1.1. To implement a quick check to increase confidence over cleaning processes at BodyBio.

2. Scope

- 2.1. This procedure applies to all cleaning of manufacturing and packaging equipment used in non-water based activities occurring at BodyBio facilities: 45 Reese Rd and 25 Driskill St.

3. Responsibility and Frequency

- 3.1. The Equipment Cleaner or designee will perform and record the cleaning in accordance with the current cleaning procedures.
- 3.2. Quality Control will perform and record cleaning verification checks as outlined in this procedure.

4. References

- 4.1. 21 CFR 110
- 4.2. 21 CFR 111
- 4.3. A guide to ATP Hygiene monitoring

5. Procedure

- 5.1. The equipment shall be cleaned in accordance with current cleaning procedures. The verification will take place prior to reassembling the equipment. Production will let Quality Control know when equipment is ready for testing.

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5.2. Quality Control will take swab samples at random spots on the cleaned equipment using the Hygiena ATP Ultra Snap Surface swabs.

5.2.1. See SOP 04-050 for directions on swabbing technique.

5.3. Each piece of equipment has different locations identified as critical points. These critical points are programmed in the Hygiena EnSURE Monitoring system.

5.4. Data collected from all equipment swabs will be tracked and trended for a minimum of a year in order to determine accurate limits for the BodyBio Facility. Until then, the Hygiena general guideline limits will be used and are as follows:

5.4.1. Pass: < 20 RLU

5.4.1.1. The control point has been properly cleaned. Proceed to sanitizing.

5.4.2. Caution: 21-59 RLU

5.4.2.1. The control point may not have been adequately cleaned. Choose to proceed with sanitizing and monitor this location for future problems, or re-clean and re-test.

5.4.3. Fail: >60 RLU

5.4.3.1. The control point was not cleaned properly and must be re-cleaned and re-tested until a Pass result is achieved. Locations with consistent Failing results will be cause for a change in the cleaning process for that piece of equipment.

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Revision History

Date	Revision	Comments
08/27/10	0	New
08/21/19	1	Updated name. Updated format. Updated titles of those responsible. Re-wrote procedure to reflect monitoring being completed using Hygiena EnSURE ATP Surface Swabs.
JAN 06 2022	2	Added the addresses of both BodyBio facilities.