

ARTISAN LABS	Environmental Monitoring Program SOP-004.3	Issued By/ Date: <i>Donnell How</i> 2/1/20
		Approved By/ Date: <i>Manu [Signature]</i> 2/1/20

1.Purpose:

To perform and identify microbiologic testing to protect the health and safety of consumers.

2.Scope:

This procedure outlines the routine process for monitoring the effectiveness of the production facilities sanitation procedures through the use of environmental sponging to ensure surfaces are not contaminated with indicating microorganisms.

3.Associates Responsible:

QC

4.Materials and equipment needed:

3M swabs with neutralizing broth

5.Associated SOP:

SOP-004.3-1A

6.Procedure:

A. Environmental Zone Program

- a. This program breaks down into four zones, identified by the proximity to product contact surfaces.
 - i. Zone 1: Anything that comes in contact with the product (i.e. storage vessels, utensils, hoppers, conveyors, scales)
 - ii. Zone 2: Non product contact areas adjacent to product or production lines: (i.e. exterior of product contact equipment such as support frames, framework, operator buttons)
 - iii. Zone 3: Non product contact areas within the processing room that are remote from production equipment or contact surfaces (i.e. drains, high traffic walkways, walls, forklift, door handles)
 - iv. Zone 4: Areas outside of production (i.e. gowning room, restrooms, floors leading into production,warehouse)

B. Frequency of Zone Swabbing and Documentation

- a. Environmental swabbing is to be conducted once a month after daily cleaning.
 - i. A minimum of fifteen (15) swabs are to be taken monthly. Heighten monitoring may occur on an as needed basis due to trending elevated results.
 - a. Minimum four (4) swabs ZONE 1

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- b. Minimum two (2) swabs ZONE 2
- c. Minimum two (2) swabs ZONE 3
- d. Minimum two (2) swabs ZONE 4
- ii. The swabbing technician will initial and date SOP-004.3 as well as document the zone, and a description of each location swabbed.

C. Sampling procedure

- a. Indicator sponges are to be taken after the daily cleaning and sanitizing of surfaces to verify the effectiveness of the lab's procedures.
- b. Associates must wear sanitized gloves as well as appropriate smocks when entering the production area.
- c. Carefully reach into the bag touching only the stick that is attached to the sponge. Pull stick out.
- d. Holding the stick in a gloved hand, apply the sponge to the desired surface. It is recommended that surface areas off 2-inch X 2-inch or more be sampled.
- e. Carefully put the sponge back into the bag. Twist stick from the sponge once in the bag and dispose.
- f. Roll the bag down tightly.

D. Testing

- a. Sponges are to be sent to outside accredited lab and tested for the following
 - i. APC
 - ii. Yeast
 - iii. Mold
 - iv. Coliform (tested once quarterly)

E. Limits

- a. Equipment and surfaces
 - i. *High*= in contact with bulk/raw materials/ open product (<100 cfu/sponge)
 - ii. *Low*= no contact (<1,000 cfu/sponge)
- b. Floors

Document history	
Version No.	Reason for change
01	New document
02	Updated cfu limit specifications

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- i. (<10,000 cfu/sponge)
- c. Air
 - i. (<150 cfu/plate)

F. Results

- a. Once results are received they are to be documented on SOP-004-3.1A.
- b. The COA must also be kept with this SOP.

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