

Guidelines for QualiTru Needle Only Sampling



1. Purpose

Following these Standard Operating Procedures, farms and processing plants may use the QualiTru aseptic sampling method to obtain a consistent and representative sample of their liquid product. This process can be used to draw samples for microbiological, regulatory, analytical, or other component testing.

2. Scope

These guidelines and SOPs apply to the QualiTru bulk tank and silo sampling used to obtain the NCIMS required sample, for Grade "A" milk or food grade liquid being.

For further questions, please feel free to contact QualiTru.

3. Responsibility

- a. Senior management is responsible for annual procedural review, training, oversight, and standards compliance.
- b. Quality assurance is responsible for management of quality system, implementation, adherence, and validation of the effectiveness/metrics, as applicable.
- c. All applicable processor personnel are responsible for adhering to this procedure to assure that controlled documents are appropriately used, updated, and distributed in accordance with this procedure.
- d. Farm or processing plant is responsible for approval and hiring of hauler/sampler training and certification, product maintenance, training, and sanitizing.
- e. Anyone who is approved and trained on the use of the QualiTru Aseptic Sampling System to collect a milk sample is responsible for understanding the content of this SOP. Training in the proper installation of the stainless QualiTru fittings, septa and general knowledge of aseptic technique is required before a person is qualified to perform this procedure.

4. Related Materials Requirements

- a. Required equipment and supplies from QualiTru.
 - i. Stainless Steel (S.S.) Sanitary Ports designed and manufactured by QualiTru to be mounted on side of the tank or silo.
 1. Contact QualiTru for your specific application.
 - ii. 7 or 12 Port QualiTru Aseptic Septa, Pn: 110011, 110021, 110064, or 110074.
 - iii. Sterile Septa cover (blue).
 - iv. Wrench to tighten the nut used to hold the septa in the S.S. fitting.
 - v. Assemble necessary items: needle, syringe, or TruDraw Single Sampler.



- b. Required items NOT supplied from QualiTru.
 - i. Alcohol used to swab the front of the QualiTru Sterile Septum, prior to needle insertion.
 - ii. Cotton swab used to sanitize front of QualiTru Sterile Septum prior to needle insertion.
 - iii. Bottle of hand sanitizer or hand sanitizer wipes.
 - iv. State approved regulatory sample container.
- c. Pre-installation items.
 - i. Application to install the QualiTru sterile sampling equipment shall be filed with the state regulatory agency and the person responsible for your operations regulatory oversight, if applicable.
 - ii. Application shall be approved before the sampling equipment is installed.
- d. System Installation.
 - i. Installation of the QualiTru non-insulated or recessed port should be completed by a welding and fabricating company that recognizes 3A and PMO standards, must be installed according to the recommendations of QualiTru engineers in a manner that is compatible with its intended use, as approved with your state regulator.
- e. System Operation.
 - i. Pre-Sample Collection Requirements.
 - ii. Collecting the producer sample.
 - iii. Sample storage requirements.

5. Related Material

- a. Most current approved PMO Revision.
- b. QualiTru SOP related to use of Sterile Septum, and QualiTru non-insulated or recessed port.

6. Procedures

- a. General Sterile Septum Installation.
 - i. Step 1: Unscrew the nut covering QualiTru stainless steel port.
 - ii. Step 2: With an alcohol saturated swab or Alcohol Wipe, clean inside of QualiTru Assembly bowl.
 - iii. Step 3: Open package containing QualiTru Sterile Septum without contaminating Septum.
 - iv. Step 4: Remove Septum from package by only touching outside rim, and not making contact with rubber portion.
 - v. Step 4: Insert Septum into QualiTru Assembly bowl.
 - vi. Step 5: Hand tighten the nut and then with wrench, **tighten the nut no more than a 1/8th inch turn.**
- b. General QualiTru Sampler Procedure.
 - i. Wash hands thoroughly.
 - ii. Remove blue dust cover.
 - iii. Swab the smooth plastic surface of the QualiTru Sterile Septum with sanitizing agent for an appropriate time (typically 15-20 seconds).



- iv. Use proper sterile technique to remove the needle from its sterile packaging,
- v. Line the needle up with one of the penetration channels and push the needle gently through the smooth plastic surface and all the way through the rubbery septum material below it into the interior of the vessel or line. (See Appendix A). Penetrate the Septum with a slight angle when sampling from the outer channels. (See Appendix A).
- vi. Carry out the transfer of material (QualiTru TruDraw Single Sampler, Sterile Collection Bag or syringe). Fill the syringe or bag with the liquid sample. If you are using a syringe, the liquid sample may be transferred to a sterile sample container. If you are using a bag, you can adjust the rate of flow with a flow clamp, different size needle or a peristaltic pump.
- vii. After the material transfer is completed, withdraw the needle, and cover it to prevent accidental needle sticks. Discard the needle properly in a container for sharps.
- viii. Place the blue dust cover over the nut.
- ix. Replace the QualiTru Sterile Septa after each channel has been penetrated. Do not reuse the channels.
- x. The Aseptic Septa can be left in place during the CIP cycle and has been validated at a combined 250°F, 150psi for 100 hours.
- xi. For an application outside these guidelines, please contact QualiTru.

7. Quality Records

- a. Associated Company Manuals, and SOP.
- b. Records of Education, training, skills and experience.
- c. Records related to the review of customer requirements.
- d. Supplier evaluation records.
- e. Product identification records.
- f. Product conformity records.
- g. Nonconformities and Corrective Action, CAPA, SCAR, NCMR records.
- h. Results of Preventative Actions taken.
- i. Wash and Sanitation records.
- j. Related forms that address PMO requirements.

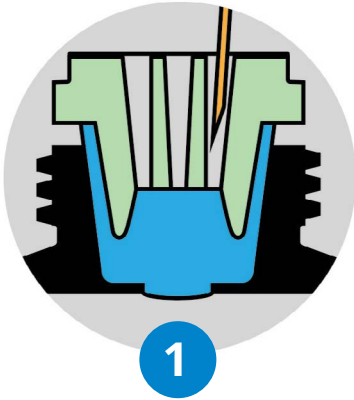
8. Forms

- a. All internal forms used for track and trace compliance to ISO, FSMA, SQF, HACCP, PMO and all others not mentioned that are applicable to the traceability of use, cleaning, and sanitizing of the QualiTru product.

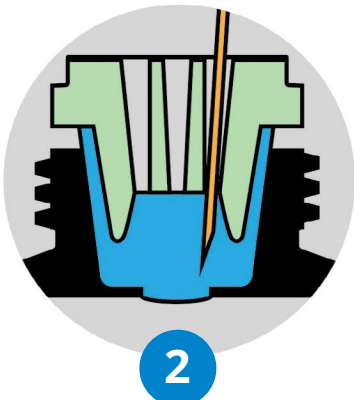
Rev	Description of Change	Revision Date	DCO#
A	Initial Release	14FEB2016	BAR02142017

Appendix A

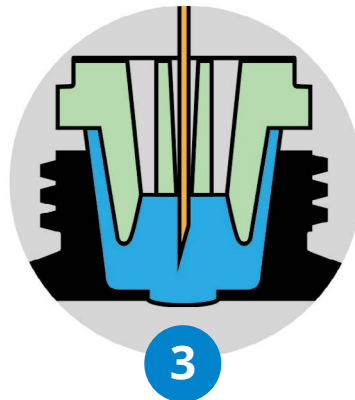
Proper Needle Insertion into QualiTru Sterile Septum



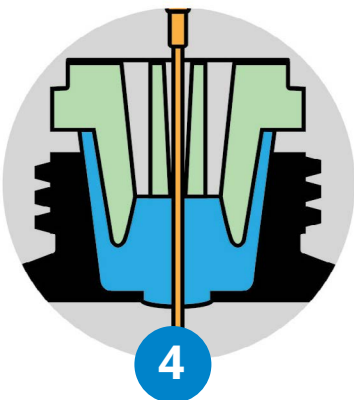
1
Line the hypodermic needle up with the channel you plan to use.



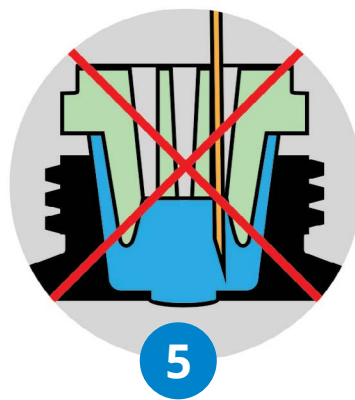
2
Face the bevel of the needle outward, or toward the outer ring.



3
Slowly push the hypodermic needle until you meet resistance.



4
Gently continue through the rubber until you can push no further.



5
Do not spin or twist on the way through, as you could core the rubber.