

Guidelines for Use of the TruDraw Single Sampler



1. Purpose:

The purpose of this SOP is to outline the general application, use and disposable of the QualiTru TruDraw Single Sampler used to draw samples for Antibiotic, (PMO: Appendix N), Microbiological, Chemical, Regulatory, analytical, or other component testing.

2. Scope:

These guidelines and SOPs apply to the QualiTru TruDraw Single Sampler 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 Sampling System and TruDraw Single Sampler to collect a fluid sample is responsible for understanding the content of this SOP. Training in the proper installation of the QualiTru Sanitary Port, QualiTru Sterile 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. Sanitary Port: QualiTru Sanitary Port, designed and manufactured by QualiTru and 3A certified, to be installed at specific points though-out the process which holds the QualiTru Sterile Septa. Contact QualiTru for your specific application.
 - ii. 7 or 12 Channel QualiTru Sterile Septa.
 - iii. Dust Cover (blue).
 - iv. Wrench to tighten the nut used to hold the QualiTru Sterile Septum in the QualiTru Sanitary Port.
 - v. Assemble necessary items: TruDraw Single Sampler.
 - vi. QualiTru 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. Disposable gloves and other PPE.
- c. Pre-installation items.
 - i. Application to install the QualiTru Sampling System 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 Sanitary Recessed Port or Sanitary Fitting 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. Pasteurized Milk Ordinance - PMO (most current revision).
- b. QualiTru SOP related to use of QualiTru Sterile Septum.

6. Procedures:

- a. General QualiTru Sterile Septum Installation
 - i. Install QualiTru Sanitary Port according to manufacturers recommendations for location and function.
 - ii. Wash hands thoroughly prior to putting on personal protective gear and disposable gloves.
 - iii. Remove nut.
 - iv. With an alcohol swab, clean out the interior housing of the port, and verify it is clean of contaminants.
 - v. Remove the QualiTru Sterile Septum from its packaging, using caution to NOT touch the food contact surface of the septum.
 - vi. Place the QualiTru Sterile Septum into the QualiTru Sanitary Port with channels exposed outwardly.
 - vii. Hand tighten the nut around the QualiTru Sterile Septum.
 - viii. Use a wrench to tighten additional 1/8 of a turn, ****Do no overtighten****, as this can damage the septum.
 - ix. Place blue dust cover over the stainless nut to protect QualiTru Sterile Septum from particles, dust and other environmental contaminants, when not in use.



b. General QualiTru Tru Draw Sampling Procedure.

QualiTru Sampling System sanitary ports, can be installed at any point throughout a producer, hauler or processor system. This general procedure applies to any sample take through a QualiTru Septum via a QualiTru TruDraw Single Sampler.

- i. Wash hands thoroughly prior to putting on personal protective gear and disposable gloves.
- ii. Gain access to the surface of QualiTru Sterile Septum, by either lifting the security lid of the recessed port on a truck or bulk tank, or simply removing the blue dust cover from a sanitary port or fitting mounted in line, or on a tank of silo.
- iii. With an alcohol saturated swab or alcohol wipe, clean the foil surface of the QualiTru Sterile Septum in the port being sampled. (Typically 15-20 seconds).
- iv. Open package containing the TruDraw Single Sampler. (See Appendix A)
- v. Remove TruDraw Single Sampler from package by only touching the body of the TruDraw Single Sampler.
- vi. Apply TruDraw Single Sampler identification to body of sampler, or prepare sticker with date, time, location, or other applicable information of sample taken.
- vii. While holding TruDraw Single Sampler, rotate the cap counter-clockwise until it stops and firmly press cap down onto top of TruDraw Single Sampler. Verify that the spikes under the cap have completely pierced the top lid of the TruDraw Single Sampler.
- viii. While holding cap against top of TruDraw Single Sampler, remove cover from the hypodermic needle by pulling it off. Keep cover so it may be re-installed after taking sample.
- ix. While holding TruDraw Single Sampler, push needle into unused channel of the QualiTru Sterile Septum, to fill TruDraw Single Sampler with fluid. (See Appendix B.)
- x. Pull container to remove needle from QualiTru Sterile Septum and carefully replace / cover of needle.
- xi. Firmly pull on cap and remove it from TruDraw Single Sampler. Safely discard of cap and needle in a sharps container.

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.



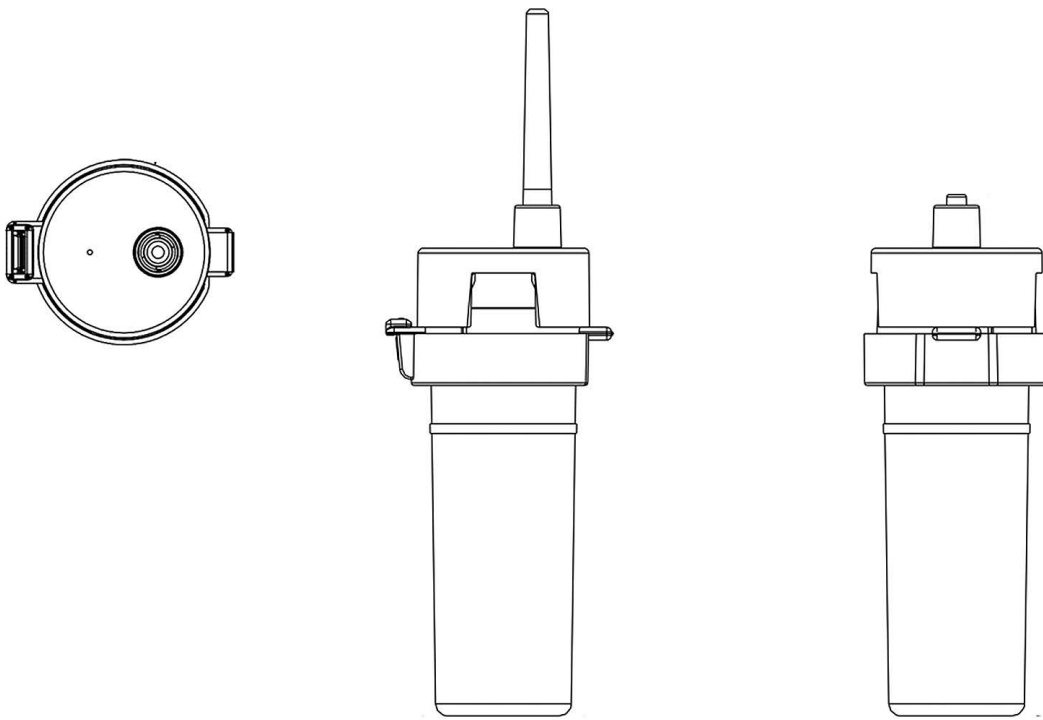
8. Forms:

- 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	27APR2017	NA

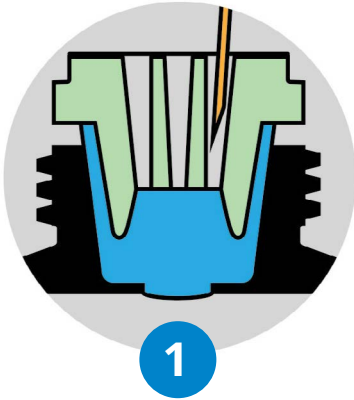
Appendix A.

***Diagram is a representation and may not reflect the exact final configuration of purchased product.

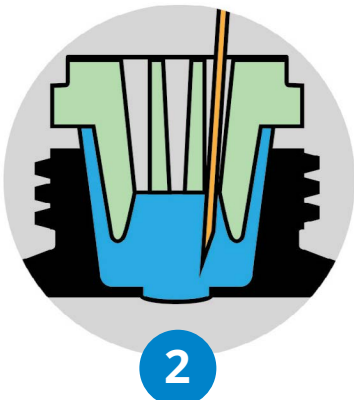


Appendix B.

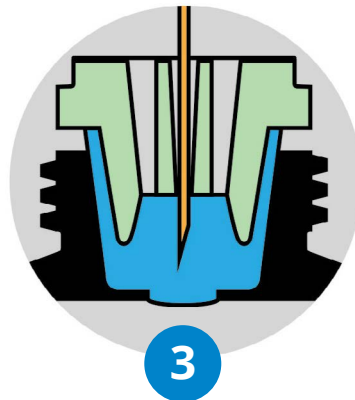
Guidelines for Proper Needle Insertion into QualiTru™ Septum



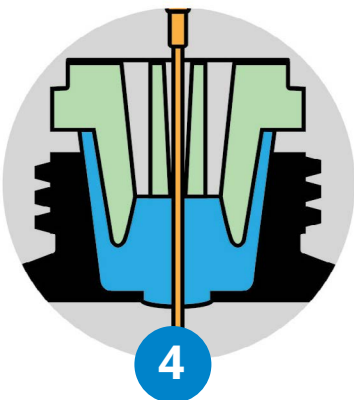
Line the hypodermic needle up with the channel you plan to use.



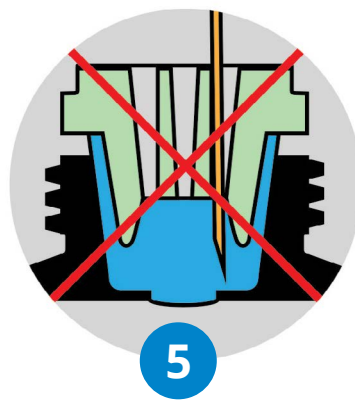
Face the bevel of the needle outward, or toward the outer ring.



Slowly push the hypodermic needle until you meet resistance.



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



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