

Guidelines & SOP for QualiTru Inline/ Direct Load Sampling System



1. Purpose

QualiTru is dedicated to giving our customers the most consistent and accurate results when it comes to sampling. When used according to this SOP, the QualiTru Sampling System gives the most accurate representative sample available for regulatory compliance, and component based payment from processors and Co-ops.

2. Scope

These guidelines and SOP apply to the QualiTru Inline Sampling System used to obtain the NCIMS required sample for milk directly loaded onto a milk tanker truck or into a bulk tank. The NCIMS approved this sampling method with the issuance of FDA MI-06-6 released May 15, 2006.

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 farm 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. Transportation/ hauling company 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 Inline Sampling System to collect a milk sample is responsible for understanding the content of this SOP. Training in the proper installation of the stainless steel QualiTru Sanitary Inspection Fittings, 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. Stainless Steel Sanitary Port (S.S) designed and manufactured by QualiTru to connect into the milk line and hold the QualiTru Sterile Septa. The Sanitary Port can be an elbow, tee, or custom built to fit your needs.
 - ii. Appropriate QualiTru Sterile Collection Bags.
 - iii. Appropriate QualiTru Sterile Septa. QualiTru can advise which Sterile Septa will work best for your application.
 - iv. Dust Cover (Blue).
 - v. Wrench to tighten the nut used that holds the Sterile Septum in the S.S. fitting.
 - vi. Peristaltic Pump.



b. Required items NOT supplied from QualiTru.

- i. Pre-Installation Items.
- ii. Refrigerator Requirements.
- iii. System Installation.
- iv. System Operation.
 1. Pre-Sample Collection.
 2. Collecting the producer sample.
 3. Splitting the producer sample.
 4. Sample storage requirements.

c. Pre-Installation Items.

- i. Application to install the QualiTru Aseptic Sampling System shall be filed with the state regulatory agency and the person responsible for your operations regulatory oversight.
- ii. Application shall be approved before the sampling equipment is installed.
- iii. Guidelines for approval application can be found in FDA issued MI-06-6 or contact your state regulatory agency or use Form A (see attached).

d. Refrigerator Requirements.

- i. The refrigerator must be the appropriate size to hold the QualiTru Sterile Collection Bag and related equipment.
- ii. Refrigerator must be able to maintain samples between 32°F to 40°F (0.0-4.5°C) to be in regulatory compliance. If the temperature falls out of range (OOR), then the samples are not useable for regulatory use.
- iii. Thermometer(s) must be used to track the refrigerator temperature and have a minimum scale of 2°F or 1°C.
- iv. Thermometer(s) of digital or liquid filled in glass type, checked annually by an NCIMS certified representative.
- v. Refrigerator temperature checked and recorded AM-PM, from thermometers located on top and bottom shelves (where applicable).
- vi. Thermometer accuracy checks and refrigerator temperature logs maintained for 2 years.
- vii. The refrigerator is used to ONLY collect and store samples and sampling related equipment.

e. System Installation.

- i. Install the QualiTru Sanitary Inspection Fitting in a position after the chiller/plate cooler, where there is a standard elbow located in an area where it will be convenient to insert the needle, attached to the tubing of the sterile sampling bag, into the sterile septum.
- ii. Location of the septum should be in a place that allows for easy changing of the septum and cleaning/sanitizing the S.S. Port.
- iii. Alternatively, the QualiTru Sanitary Inspection Fitting can be located in a straight run of the line or customized with a custom piece that will meet your system needs.
- iv. The refrigerator must be located within a distance where the needle can be inserted into the sterile septum and the sterile bag can be placed in the refrigerator. It is strongly recommended you get a sterile sample bag from QualiTru to make sure the locations of the sterile septum and the refrigerator work properly.
- v. You will need a 120V power outlet to power the peristaltic pump and refrigerator.



f. Peristaltic Pump.

- i. The peristaltic pump comes with a clam shell head.
- ii. Open the clam shell head by pulling up on the front of the head.
- iii. Place the peristaltic section (larger "soft" portion) of the sterile sampling bag tubing over the rollers of the pump and close the clam shell head. (Make sure the peristaltic section is centered on the shell rollers).
- iv. Make sure that the rotation of the pump rollers are correct, so that it is pulling the milk from the milk line into the sterile sampling bag.
- v. Verify the number on the pump dial or keypad matches the speed at which it was calculated to give the appropriate sample size.
- vi. It is suggested the pump keypad be locked. That will prevent any inadvertent changing of speed or pump roller rotation on the pump.

5. Related Material

- a. PMO 2015 Revision.
- b. QualiTru SOP related to use of QualiTru Inline Sterile Sampling System.

6. Procedures

a. General QualiTru Sampling Procedure.

- i. Wash hands thoroughly.
- ii. Remove Dust Cover (Blue).
- iii. Swab the smooth plastic surface of the QualiTru Sterile Septum with sanitizing agent for an appropriate time period (typically 15-20 seconds).
- iv. Use proper aseptic technique to remove the needle from its sterile packaging.
- v. Line the needle up with one of the sampling 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 B). Penetrate the QualiTru Sterile Septum with a slight angle when sampling from the outer channels. (See Appendix B).
- vi. Carry out the transfer of material (TruDraw Single Sampler, sterile sampling 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 Septum after each channel has been penetrated. Do not reuse the channels.
- x. The QualiTru Sterile Septum 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. Pre-Sample Collection Requirements

- a. Sample collection container must meet NCIMS, PMO, and state regulatory agency approval. The QualiTru Sterile Collection Bag is shipped sterile and must be maintained in sanitary conditions.
- b. Size of the sample needs to be determined with cooperation of the state milk regulatory agency.
- c. Sample size obtained is to be kept to $\frac{3}{4}$ (three quarters) or less of the total volume of the sample container being used.
- d. Person(s) performing the following steps must possess a valid milk receiver or bulk milk hauler/sampler license as defined in the current edition of the NCIMS, PMO, and issued by the state regulatory agency.
- e. Person(s) performing the following steps must wash and sanitize their hands before handling the equipment used to collect the milk sample.

8. Collect the Producer Sample

- i. At the start of milking and the filling of a new empty trailer or bulk tank, place a QualiTru Sterile Collection Bag in the refrigerator.
- ii. Place the peristaltic section (larger "soft" portion) of the bag tubing into the clam shell pump roller head.
- iii. Align the tubing with the rollers and close the clam shell head.
- iv. Remove the QualiTru dust cover protecting the QualiTru Sterile Septum. Place cover in refrigerator.
- v. Swab the smooth surface of the QualiTru Sterile Septum with an approved sanitizing agent for the appropriate time following sanitizer instructions or recommendations.
- vi. Make sure the white covering over the septum remains in place until all channels are used.
- vii. Using proper aseptic technique, remove the needle from its sterile packaging or cover.
- viii. Place the needle cover in a sterile milk vial sample container and place in the refrigerator.
- ix. Line the needle up with one of the unused septum needle channels, with the bevel of the needle facing outwards from the center, and gently push the needle in until the shoulder of the needle is pressing against the white septum covering. (See Appendix B)
- x. When using the outer Septum Channels, insert the needle with a slight angle. With the bevel of the needle slanted outwards from the center. (See Appendix B)
- xi. Start the peristaltic pump, double check the speed and roller rotation are at the pre-determined settings.
- xii. After the milking cycle is complete or the tanker truck or bulk tank is full, turn off the peristaltic pump. Remove the needle from the septum and put the needle cover back on the needle. Place the QualiTru dust cover back on the nut of the QualiTru Sanitary Inspection Fitting.
- xiii. Place the QualiTru Sterile Collection Bag and tubing in the refrigerator for use at the next milking cycle or if the tanker truck or bulk tank are full, to store the QualiTru Sterile Collection Bag unit the sample is split into sample vials.
- xiv. If the tanker truck or bulk tank are not full and requires subsequent milking's to fill, follow the exact procedures as stated above starting from "Collecting the Producer Sample" until the milk tanker truck or bulk tank are filled.



- xv. The QualiTru Sterile Septum can be cleaned in place (CIP) when the milking system is cleaned. Replace the septum after all the sampling channels have been used. Hand tighten the nut that holds the septum then using the wrench, tighten the nut another $\frac{1}{4}$ (quarter) turn. Check for tightness periodically, but **DO NOT** over tighten septum.
- xvi. The opening where the QualiTru Sterile Septum seats in the QualiTru Sanitary Inspection Fitting must be hand cleaned after all the ports have been used.

b. Splitting the Producer Sample.

- i. Check and record the refrigerator temperatures using the certified thermometers supplied in the refrigerator on the upper and lower areas of the unit.
- ii. Remove the QualiTru Sterile Collection Bag containing the producer sample from the refrigerator that corresponds to the tanker truck being picked up.
- iii. Properly agitate the QualiTru Sterile Collection Bag sufficiently to obtain a representative sample. Holding the bag in a vertical position with the sample tubing on the top side of the bag, semi rapidly inverting the QualiTru Sterile Collection Bag top side to the bottom while still in a vertical position then back to its vertical position. Perform this motion semi rapidly **25 times**. Be sure to visually verify the butter fat is cascading upwards after each inversion and mixing thoroughly and evenly.
- iv. After the 25th inversion and the bag's tubing is at the top vertical position, continue to hold the bag in the vertical position and take the sanitized scissors and cut the off about 6 inches from the bag.
- v. Prepare the sample vials you are going to use to transfer the milk from the QualiTru Sterile Collection Bag.
- vi. Invert the QualiTru Sterile Collection Bag and let the milk run out the tubing for a few seconds.
(NOT INTO YOUR VIAL)
- vii. Open the tops of the sample vials you have prepared and let the milk flow into the sample vials until the vials are no more than $\frac{3}{4}$ (three fourths) full.
- viii. Close the cap on the sample vials and place the sample vials in the sample refrigerator or cooler, in a float. The cooler should have a water, ice mixture to keep the samples at the **required temperature**.
- ix. The transfer of the milk from the QualiTru Sterile Collection Bag to the sample vials needs to be completed within 3 minutes after the final agitation of the QualiTru Sterile Collection Bag.
- x. Consult your Co-op, state, or hauler to find out the appropriate information that needs to be put on the QualiTru Sterile Collection Bags and the sample vials.

c. Storage of Samples.

- i. Store the samples in the sample collection refrigerator or another state milk regulatory agency approved storage location until the tanker leaves the dairy farm.
- ii. The samples shall accompany the loaded milk tanker truck to the milk plant, receiving station, or transfer station receiving the milk.
- iii. Duplicate samples may be taken for pick-up and tested by the producer's milk handling company or State Milk Regulatory Agency.



9. 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 Appendix B requirements.

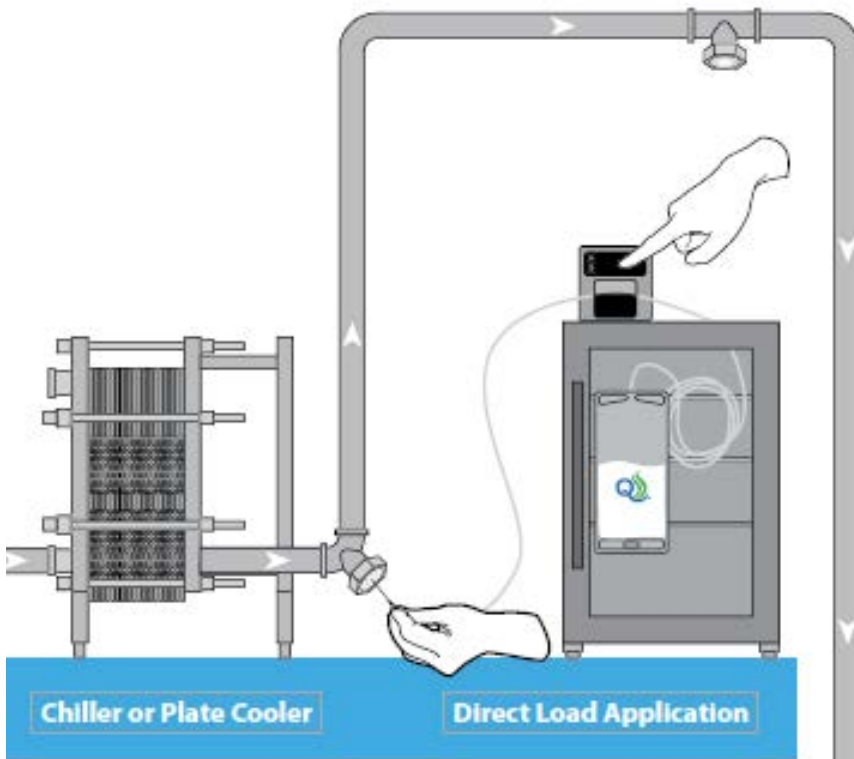
10. Forms

- 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		

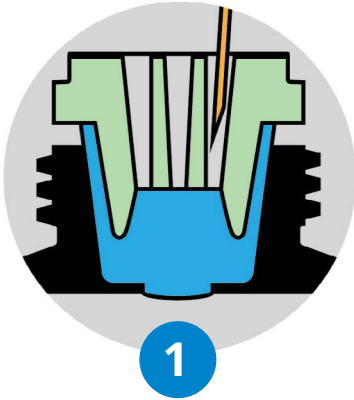
Appendix A.

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

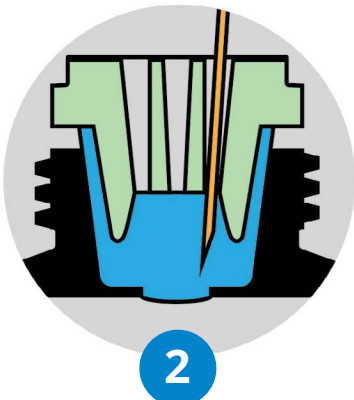


Appendix B

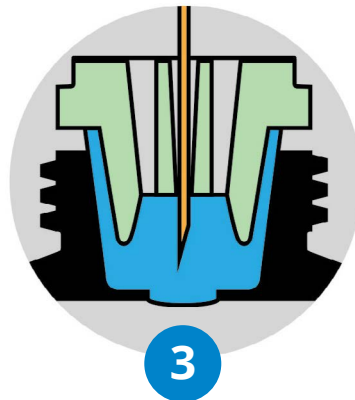
Proper Needle Insertion into QualiTru Sterile Septum



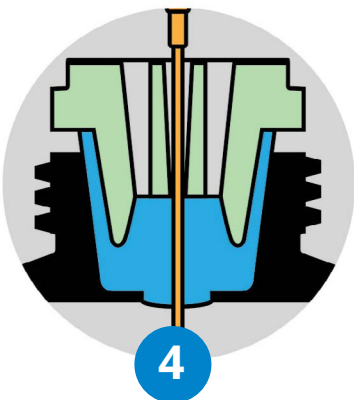
1
Line the hypodermic needle up with the channel you plan to use.



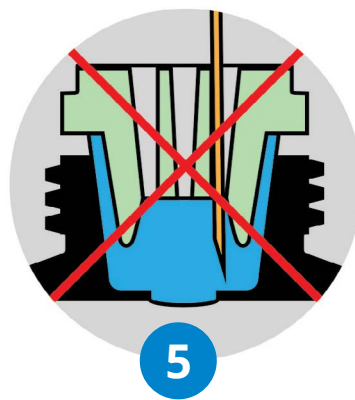
2
Face the bevel of the needle outward, or toward the outer ring.



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.