

Guidelines for Pen or String Sampling with a Peristaltic Pump



1. Purpose

As dairies become larger and herd sizes continue to expand, producers must implement various strategies in order to manage their mastitis control plans, and stop the spread of pathogenic organisms that can directly affect milk product and herd health.

2. Scope

These guidelines and SOPs apply to the pen/string sampling via a QualiTru Sanitary Fitting, Sterile Septum, Sterile Collection Bag and portable peristaltic pump to aid and contribute to a farm or dairy's Mastitis control plan.

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 producer 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 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 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 3-A certified, to be installed at specific points throughout the process. The Port holds the QualiTru Sterile Septa in place. 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.



- 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 personal protective equipment.

- 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 Port should be completed by a welding and fabricating company that recognizes 3-A 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 String Sampling Techniques via a peristaltic pump
 - i. Establish a testing scheme either by barn, pen, or an original planning system that will identify specific groups to be tested.
 - ii. Install the QualiTru fitting on the "positive pressure" side of the milking system, between the milk transfer pump and the bulk tank.

(See Appendix A)

1. QualiTru sanitary fitting can be tri-clamped or welded directly off the receiver in either an elbow or straight pipe configuration.
2. Mount the peristaltic pump within 18 inches of the Septum.
3. Place an ice chest or pail within 18 inches of the pump, for the bag to rest in as it fills.



- iii. At the beginning of each pen:
 1. Wash hands thoroughly prior to putting on personal protective gear and disposable gloves.
 2. Place the peristaltic section (larger “soft” portion) of the bag tubing into the clam shell pump roller head and close over the tubing.
 3. Remove the QualiTru dust cover protecting the QualiTru sterile Septum.
 4. Swab the smooth surface of the QualiTru sterile Septum with an approved sanitizing agent for the appropriate time following sanitizer instructions or recommendations.
 - a. Make sure the white covering over the septum remains in place until all channels are used.
 5. Using proper aseptic technique, remove the needle from its sterile packaging or cover.
 6. 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)
 7. 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)
 8. Start the peristaltic pump, double check the speed and roller rotation are at the pre-determined settings to fill the 2 liter bag about 3/4th full, or 1500 milliliters.
 - i. Avoid cross-contamination from one pen to the next:
 9. At the end of the specific pen, stop the pump, and pull the needle from the septum.
 10. Switch sterile Collection Bags when cows from new pen go on-line.
 11. Be sure milk from previous pen is evacuated from the milk lines and receiver jar before beginning to collect from new pen. Allow receiver jar to be emptied 3-4 times to flush out milk from old pen.
 - ii. Be sure to obtain an accurate pen inventory at the time of the sampling.
- b. General QualiTru Sterile Septum Installation
- i. Install QualiTru Sanitary Port according to manufacturer’s 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 not 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.



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

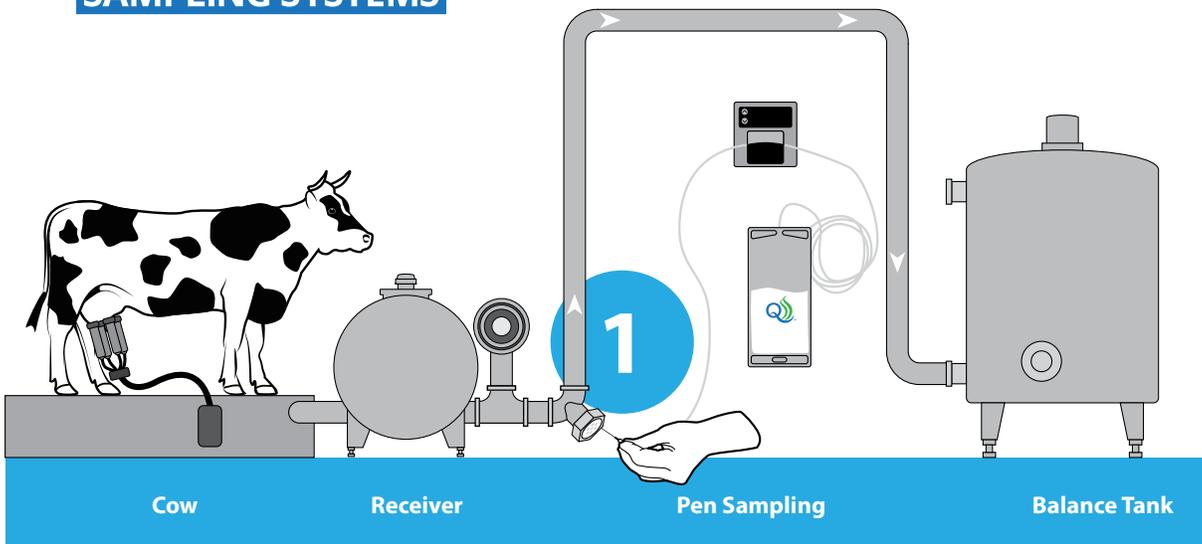
- a. All internal forms used for track and trace compliance to ISO, FSMA, SQF, HACCP, PMO and all others not mentioned that are applicable to the traceability of use, cleaning, and sanitizing of the QualiTru product.

| Rev | Description of Change | Revision Date | DCO# |
|-----|-----------------------|---------------|------|
| A | Initial Release | 18APR2017 | NA |

Appendix A. Pen Sampling Site.

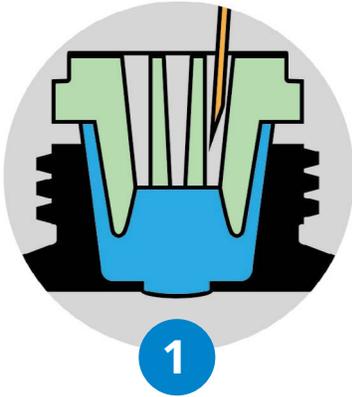


APPLICATION SITES

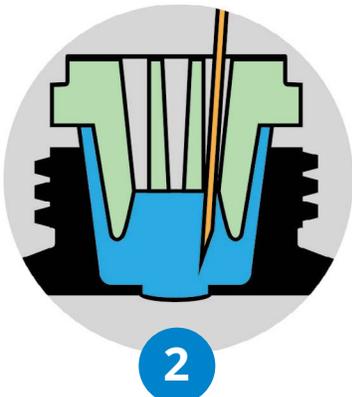


Appendix B

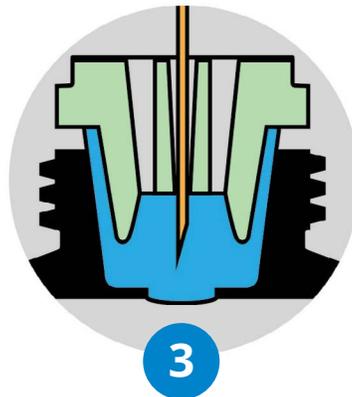
Proper Needle Insertion into QualiTru Sterile Septum



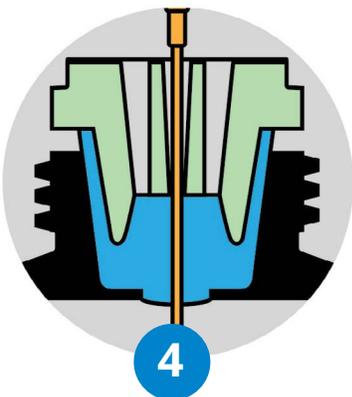
Line the hypodermic needle up with the channel you plan to use.



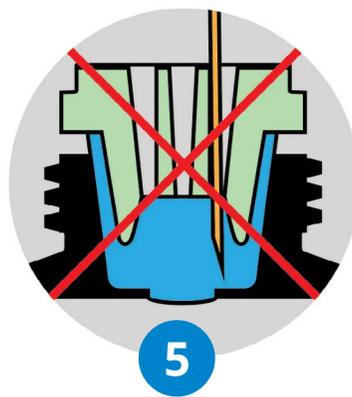
Face the bevel of the needle outward, or toward the outer ring.



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.