

M-I-18-11

February 27, 2018

TO: Director, Office of State Cooperative Programs
Attn: All Staff, Division of Milk Safety

FROM: Milk and Milk Products Branch (HFS-316)

SUBJECT: Alternate Procedure For Granting Conditional Certification For New Or Existing Laboratory Methods To Milk Analysts That Are Currently Certified For A Similar Existing Laboratory Method

The issue of granting conditional certification to milk laboratory analysts outside of the traditional on-site laboratory survey and split sample performance evaluation process has been discussed by FDA's Laboratory Proficiency and Evaluation Team (LPET) and the NCIMS Laboratory Committee. The traditional procedure/route for certification is still preferred. However, an alternate procedure/route to gain conditional certification for specific new or similar existing laboratory methods will be recognized by both LPET and the NCIMS Laboratory Committee. Applicable newly accepted/approved and some existing laboratory methods are those that essentially utilize the same or very similar methodology as previously accepted/approved laboratory methods. A Proposal will be submitted by LPET to the 2019 NCIMS Conference for inclusion of this alternate procedure in the Evaluation of Milk Laboratories (*EML*).

Conditional certification will be recognized for specifically identified and linked current and newly accepted or similar existing laboratory methods when the following criteria are met. Refer to the laboratory methods list below.

1. The analyst **shall** have conditional, provisional or full certification status for the currently accepted/approved laboratory method.
2. If analysts do not have certification status for the current laboratory method, then the traditional route of certification as specified in the *EML* will be required to be followed to gain conditional certification for the new laboratory method or similar existing laboratory method.
3. If laboratories have one (1) or more analysts certified for the current laboratory method and are seeking conditional certification for the new laboratory method or similar existing laboratory method, then the laboratory **shall** contact their Laboratory Evaluation Officer (LEO) to request conditional certification for the new or other similar

existing laboratory method and **provide** a list of analysts for which the laboratory is seeking conditional certification.

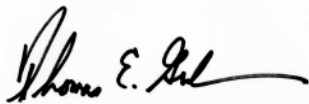
4. The laboratory shall provide documentation, e.g. training records, showing that analysts have been trained on the laboratory method for which conditional certification is being requested and assure that they understand any differences that may exist between the laboratory method and similar existing laboratory method. Verification of technique and understanding will take place at the next on-site laboratory survey.
5. Conditional status of the analyst will remain in effect until the analyst has satisfactorily participated in an on-site laboratory survey **AND** has satisfactory results in a milk split sample performance evaluation for the new laboratory method or similar existing laboratory method, at which time the analyst will be granted full certification.
6. If an on-site laboratory survey or milk split sample performance evaluation results are unsatisfactory prior to gaining full certification, then conditional certification status shall be revoked until the next on-site is satisfactory or the analyst has satisfactory results in the next milk split sample performance evaluation for the new laboratory method or similar existing laboratory method, at which time conditional status will be regained. As before, regaining conditional certification shall be by the route that certification was lost.
7. The laboratory **shall agree** to these conditions or the traditional procedure/route of certification will be required to be followed.
8. LEOs will need to submit a Laboratory Status Change Summary Template to LPET to include the new laboratory method for the laboratory. An on-site survey and evaluation report **will not** be required if conditional certification is granted by meeting Items 3 and 4 above.
9. Should a supplemental or the biennial on-site laboratory survey take place at any time up until the laboratory's expiration date, then an evaluation report and summary template will be required to be submitted to LPET. The new laboratory method or similar existing laboratory method shall be part of the on-site laboratory evaluation or certification shall be removed or reduced as appropriate.

To initiate this process, the following pairings will be recognized:

| # | Currently Accepted/Approved | New/Other Similar |
|---|---|---|
| 1 | Petrifilm Aerobic Count (PAC) | Petrifilm Rapid Aerobic Count (RAC) |
| 2 | Charm Beta lactam SL or SL3 | Charm ROSA SULF, ROSA TET or TRIO |
| 3 | Neogen Advanced for Tetracycline or B-l | Neogen Advanced for Beta lactams or Tet |
| 4 | Any currently approved Electronic Somatic Cell Count (ESCC) | Any other current or new ESCC (excluding Foss BacSomatic) |
| 5 | Idexx Colilert or Colisure | Idexx Colilert or Colisure |

An electronic version of this memorandum is available for distribution to FDA Milk Specialists, Milk Regulatory/Rating Agencies, Laboratory Evaluation Officers and Milk Sanitation Rating Officers. This electronic version should also be widely distributed to representatives of the dairy industry and other interested parties and will be available on the FDA Web Site at <http://www.fda.gov> at a later date.

If you would like an electronic version of this memorandum prior to it being available on the FDA Web Site or NCIMS Web Site, please e-mail your request either Thomas.Graham@fda.hhs.gov or to Robert.Hennes@fda.hhs.gov.



Thomas Graham, PhD
Team Leader
Laboratory Proficiency and
Evaluation Team



Robert F. Hennes, RS, MPH
CAPT, U.S. Public Health Service
Milk and Milk Products Branch