Proposed change to CDCB Auditing Procedures for Laboratories

Submitted by Dairy One Cooperative, Ithaca, NY

Proposal:

Dairy One proposes changing the CDCB Auditing Procedures for Laboratories so that laboratories would have the option to generate butterfat test results that are based on full spectrum analysis. The current requirement only allows the use of "B" wavelength information.

Identifying butterfat content by specific wavelengths was the original approach used by mid-infrared analyzers (Barbano et. al). This approach is why the current guidelines require the "B" wavelength. At some point, the industry decided to specify that the "B" wavelength needed to be used instead of the "A" or "A/B" wavelength options. In the late 1990's FTIR units were made commercially available. These units produce the full infrared spectra for each sample and then derive values of fat, protein, etc. from this full spectra data (Barbano et al).

A study by FOSS comparing (full) Spectral Calibration with Traditional Calibration (wavelength specific) for butterfat found that the coefficient of variation (CV) was lower for the Spectral Calibration than the Traditional Calibration (FOSS). Since CV is a measure of accuracy, these results indicate that Spectral Calibrations are more accurate in determining butterfat content than the Traditional Calibration.

The FOSS study also concluded that differences in sample temperature will have less impact on fat results tested using the Spectral Calibrations compared to the Traditional Calibration approach (FOSS). This suggests using Spectral Calibrations improves the robustness of the testing process.

Since using the Spectral Calibration approach improves result accuracy and testing robustness, Dairy One believes that it is a valid technology and that it should be allowed as an option to the use of the "B" wavelength requirement. Under this proposal, laboratories could continue to use the "B" wavelength testing option based on their preference.

References:

Barbano, Melilli, Overton; Advanced use of FTIR spectra of milk for feeding and health management; Cornell University, accessed via Cornell ecommons: https://ecommons.cornell.edu/bitstream/handle/1813/37978/CNC2014_14_Barbano.pdf;sequence=1

FOSS; MilkoScanFT 6000 Fat Measurement, Spectrum Calibration vs. Traditional Calibration; Issue 76100-31bGB, November 1999

Butterfat Analysis~~and "B" Filter~~

All IR analyzers must use either a "B" wavelength or full spectral calibration.~~.~~

Protein References

Throughout this manual, all references to protein are references to the true protein values.

Reporting False Sample Readings

Laboratories are prohibited from submitting false sample analysis results in place of actual machine results for high or low sample readings.

Decertification Procedures

Decertification will only be considered when the performance of a laboratory has fallen below the minimum standards established by CDCB and the organization does not take prompt action to return to compliance within the time period specified by the auditor.

Decertification Appeals

For policies and procedures on decertification appeals, please refer to page 7 of the 'General Auditing Guidelines' for a detailed protocol.

Approval Protocol for New Laboratory Instrument(s) and Component(s)

DHI laboratories certified under the CDCB *Auditing Procedures for Laboratories* are required to demonstrate acceptable analytical performance on all lines of test instruments (also known as analyzers) on a routine basis. The monthly Samples Unknown program administered by the QC Program Manager serves this role for existing laboratory instruments.

Certified laboratories replace or add a new line(s) of instruments on a routine basis. This procedure applies to new, used, and refurbished instruments. Results from these new instruments may not be submitted to the Genetic Evaluation Program (GEP) until demonstration of satisfactory instrument performance is completed.

New Instrument Approval Protocol

1. As outlined in the *General Auditing Guidelines*, the new instrument(s) must be reported to QC Program Manager and subsequently enrolled in the monthly Samples Unknown program. For each new instrument, the following information should be provided:

    a. Manufacturer,
    b. Model,
    c. Condition (new, used, refurbished),
    d. Serial number,
    e. Components to be analyzed (fat, protein, SCC, MUN, other),
    ~~e.~~f. Fat analysis (if applicable) using "B" wavelength or full spectra,
    ~~f.~~g. Instrument(s) to be replaced/taken out of service (where applicable).

2. If laboratory management and instrument technicians are not familiar with the make and/or model of the instrument, appropriate installation and training by the respective instrument manufacturer must be provided. Written evidence of this training must be forwarded to QC Program Manager.

3. The instrument must be appropriately calibrated using suitable reference controls. Samples Unknown sets and pilot samples are not suitable reference controls for calibration of any instrument.

4. The laboratory will remain certified provided the laboratory completes one of the following options.

    a. Laboratory submits documentation to the QC Program Manager that includes the documentation listed below. Submission of data to the GEP from the new instrument(s) may begin immediately when using this option.

        - Completed manufacturer's training checklist,
        - Results from one set of Samples Unknown run by the laboratory during the instrument installation,
        - Documentation of calibration check validation during the first three consecutive weeks of operation, and
        - Log files/reports for daily and hourly checks of multiple ranges of components, SCC, and zeroes during the first three consecutive weeks of instrument operation.