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MEMORANDUM

TO: QA PROGRAM

FROM: AMANDA BOLDOC, ALCOHOL PROGRAM SUPERVISOR 

SUBJECT: NONCONFORMING WORK: QC DATA FOR STANDARD VERIFICATION

DATE: 7/16/2015

On July 15, 2015, an aqueous ethanol control standard verification for Cerilliant Ethanol-80, lot FN09051304 was performed on the Teledyne Tekmar HT3 Headspace autosampler/Agilent 6890N GC-FID. Due to insufficient volume of 0.080 g/100 ml aqueous ethanol QC material for this run as defined by ALC_P100 section 4.4.2, two alternative QC materials were included in the analytical batch: Cerilliant Ethanol-10 (0.010 g/100 ml ethanol), lot FN080612-04, and Cerilliant Ethanol-300 (0.300 g/100 ml ethanol), lot FN121510-01. These certified reference materials fall within the range of the calibration performed at the beginning of the analytical batch and bracket the intended concentration of QC material, thereby acting as a substitute for the aqueous control. Additionally, due to limited quantity, a single vial of previously-verified 0.080 g/100 ml aqueous ethanol QC material (Cerilliant Ethanol-80, lot FN011712-02) was included in the analytical batch for comparison to the new lot number being verified. No case samples or other materials were included in this batch due to the nonconformity.

Both aqueous control levels and all calibration check samples were shown to meet the quality control criteria as defined in ALC_P100 section 11.1. The new material lot was shown to fall within 5% of the manufacturer's stated target value.