Helix Biological Laboratory
Quality Assurance /Quality Control Plan
Microbial Source Tracking Analysis:

1) Upon reception, samples are examined to make certain there is no damage or leakage during shipment. Samples are examined to ensure that sample names/IDs on the chain of custody form match sample names/IDs on sample container labels. Sample names/IDs are recorded and samples are properly stored and secured prior to sample processing.

2) All reagents used in DNA extraction and quantitative real time PCR are verified to be well within their expiration date of use and are guaranteed to produce optimal results regarding their application.

3) Prior to performing analysis, the quantitative real time PCR instrument is properly calibrated, and must pass all start up diagnostic check point tests to ensure proper function of the instrument and verify performance. Bioinformatic software used by the quantitative real time PCR instrument must also pass diagnostic check to ensure proper data collection.

4) Negative control samples are run simultaneously with test samples to ensure against false positive results. All negative control samples must produce a “no amplification” result.

5) Upon conclusion of performing quantitative real time PCR analysis, all data is carefully reviewed for accuracy and reviewed for any anomalous data values.

6) Any anomalous data values or negative control samples that produce amplification are immediately noted and measures taken to solve the issue and to repeat the analysis on the samples in question.