Strategies to Identify and Eliminate Contamination in the Molecular Testing Laboratory

Diagnostic tests that amplify nucleic acids (e.g. PCR) are highly sensitive procedures capable of detecting small quantities of target DNA. During amplification ≥10^9 copies (amplicons) of target DNA may be produced. Therefore, laboratories must implement stringent quality control procedures to prevent contamination of the laboratory and generation of false-positive results. The following guidelines are intended to help laboratories identify, eliminate, and minimize future risk of DNA contamination.

How to recognize contamination:

- Look for an increase in positivity rates for low prevalence organisms.
- Numerous "low level" positives (e.g. just above the cut-off values).
- Unusual patterns of "out of season" positives (e.g. RSV in the summer months).
- Results that do not fit the clinical diagnosis.
- Perform periodic environmental testing (e.g. swab testing).

What to do when you suspect amplicon contamination:

- Determine what areas, instruments, or reagents are contaminated through environmental wipe testing.
- Use fresh 5-10% bleach (shown to be the most effective means to remove amplicon contamination) to disinfect contaminated surfaces. After drying, remove bleach residue by wiping with 70% alcohol (isopropyl or ethanol).
- Dispose of affected test reagents and kits.
- Rigorously clean (at least 3 consecutive days) contaminated areas (especially handles, door knobs, light switches, etc.).
- It may take days or weeks to remove lab contamination depending upon the level of contamination present.
- Monitor positivity rates. Retest low level positive specimens.

Strategies to minimize risk:

- Store testing reagents in a designated "clean" area free from positive controls and patient specimens.
- Have dedicated lab supplies, pipettes, PPE, refrigerators/freezers for pre-PCR, sample processing and amplification areas. Color code if possible.
- Practice unidirectional workflow.
- Use aerosol resistant pipette tips.
- Daily decontamination with 5% bleach followed by ethanol wipe.
- Process one specimen at a time with frequent glove changes.
- Paper and pens can become contaminated. Do not move between areas.
- Aliquot reagents into small working volumes for storage.
- Consider bagging (Ziploc) or segregating used molecular test cartridges. Handle with gloves and then dispose immediately afterwards.