

## Appendix A

### Diagnostic TRL Statements:

#### PCR Assay TRL Definitions

- 1 = Requirement identified, molecular targets not defined or not yet identified. May require basic research (sequencing, etc.)
- 2 = Potential target sequences identified, but no lab testing. Paper chemistry only.
- 3 = Initial assay development and evaluation. Assay design (primers, probes) and assay format (TaqMan, FRET, etc.) locked down
- 4 = Home brew assay. Buffer only, no scale-up, not optimized on any real-time platform
- 5 = Bench scale pilot reagent manufacturing with some mfg. controls. Not fully qualified/validated, but some testing in relevant sample types.
- 6 = Some degree of validation in relevant sample matrices, but only in expert user hands. CB.56 data package in development.
- 7 = CB.56 data package complete and on file. More complete validation, plus multiple lots manufactured and tested by users outside developing lab in relevant sample types. Ideal transition point.
- 8 = Fully validated, tested by end users under operational conditions, eligible for FDA clearance/approval, IDE.
- 9 = FDA-cleared/approved (clinical diagnostic applications only) or otherwise independently validated/accepted (e.g., AOAC, USDA, CDC).

#### Immunoassay TRL Definitions

- 1 = Requirement identified, antigenic targets not yet identified or no antibodies available. May require basic research (sequencing, etc.)
- 2 = Potential antigenic targets identified, but no lab testing, or antibodies being generated or still at crude serum stage. Reagent performance not yet characterized for utility.
- 3 = Initial assay development and evaluation. Assay design (antibodies or other ASR's\*) and assay format (e.g., handheld vs. instrument based, sandwich, competitive, etc.) locked down
- 4 = Home brew assay. Buffer samples only, no scale-up, optimized on at least one platform
- 5 = Bench scale pilot reagent manufacturing with some mfg. controls. Not fully qualified/validated, but some testing in relevant sample types.
- 6 = Some degree of validation in relevant sample matrices, but only in expert user hands. CB.56 data package in development.
- 7 = CB.56 data package complete and on file. More complete validation, plus multiple lots manufactured. Assay tested by users outside developing lab in relevant sample types. Ideal transition point.
- 8 = Fully validated, tested by end users under operational conditions, eligible for FDA clearance/approval, IDE.
- 9 = FDA-cleared/approved (clinical diagnostic applications only) or otherwise independently validated/accepted (e.g., AOAC, USDA, CDC).

\*ASR = Analyte-specific reagent