Assay Development Design Inputs

☐ Design Inputs defined below have been superseded by Design Inputs Dated:_____

Complete the Design Inputs for the project with as much detail and unambiguity as possible.

Date:_____ Project Number:_____

Customer:_____ Project Name:_____

Project Manager:_____

NOTE: Verifiable Inputs are defined in Section 4. All other sections provide required information for design and development of the project.

1. Target(s) to Detect:

☐ Antibody(ies) ☐ Antigen(s)/Biomarker(s)

Details/Comments:_____

a) Target Information:

	Name/Description	Size (kDa)
Target		

Target/Samples Provided By:

☐ Customer Provided ☐ Sourced by BioAssay Works

Customer must provide safety, handling, and storage documentation for all samples provided (SDS, BSL statement, expiration/stability, storage conditions of sample prior use and remainder of sample after use, etc.)

b) Antibodies/Analytes Required for Detection:

☐ Customer Provided ☐ Sourced by BioAssay Works

Customer must provide safety, handling, and storage documentation for all Antibodies/Analytes provided (SDS, BSL statement, expiration/stability, storage conditions prior use and remainder of sample after use, etc.)

Antibodies/Analytes for Detection:

Name	Host Species	Poly/mAb	Ig Class	Quantity* (mg/µg)
Comments:				

* BAW requests a concentration of ≥ 2 mg/mL for screening. BAW will not concentrate reagents, and lower concentrations may limit development options.

2. Assay Format:

a) Select preferences – If one option is preferred, and the other option is acceptable, record a "P" in the box of the preferred option, and an "A" in the box of the acceptable option:

☐ Cassette Based	☐ Dipstick	☐ No Preference
☐ Qualitative (Yes/No Assay)	☐ Semi-Quantitative (Reader)	☐ No Preference
☐ Sandwich Assay	☐ Competitive Assay	☐ No Preference

Additional Information:_____

b) Test Environment – Where will the assay be performed (laboratory, point-of-use, etc.)? Describe environmental factors that may influence assay performance (temperature, humidity, etc.)

Please describe:_____

3. **Sample to be Tested:**
   a) Sample Matrix (serum, blood, urine, etc.) – Please Describe:_____
   _____
   b) Sample Handling, Treatment, Collection Expectations/Requirements – Please Describe:
   _____
   _____
   c) Buffer Requirements/Formulation – Please Describe:_____
   _____
   _____
   d) Volume of Sample Typically Available for Testing:_____µL
   (See Table in Section 4. DESIGN INPUTS, below for Ideal and Acceptable sample volumes to apply to the test.)

4. **DESIGN INPUTS (Verifiable Inputs) - Assay Performance:**
Please indicate requirements for assay performance in the table below. Be as specific and precise as possible. If any parameter does not apply or no preference is currently expressed, please leave blank. If additional inputs are determined, revise table to include.

Parameter	Optimal Requirement IDEAL	Minimal Requirement ACCEPTABLE	Rank 1 = Crucial 2 = Important 3 = Desirable
Sensitivity: LOWER Limit of Detection			
Sensitivity: UPPER Limit of Detection			
Specificity: Cross-Reactivity (List analytes to test for Cross Reactivity)			
Reproducibility (Between lots – multiple lots must be produced to verify this input. Sample concentration and ideal/acceptable deviation must be listed.)			
Accuracy/Correlation (To industry standard or accepted testing method – list testing method, sample concentration, and ideal/acceptable correlation)			
Statistical Method (To be used to verify inputs, e.g. using C=0, an AQL of 1.0 applied to a standard lot size produces a confidence level of at least 99% acceptable results)			
Sample Size (µL) (Volume to apply to the test)			
Time to read results (minutes)			

5. **Customer Requirements/Requests** (General information to prepare for design transfer and production)

Parameter	Optimal Requirement IDEAL	Minimal Requirement ACCEPTABLE	Rank 1 = Crucial 2 = Important 3 = Desirable
Stability/Shelf-Life (typically, an option offered by BAW)			
Estimated Standard Lot Size			
Storage Conditions			
Shipping Conditions			

6. **Risk Management:** (Record analysis of potential hazards. If 'Moderate', 'Hazardous', or 'Severe', describe potential hazards or risks.)

a) Potential Hazards from Materials and Samples – Safety Concerns for BAW personnel and end users:

☐ Minor ☐ Moderate ☐ Hazardous

Describe:_____

_____

_____

b) Potential Risks of Inaccurate Test Results or Incorrect Test Analysis (false positives, false negatives, incorrect interpretation of results, possible user errors, etc.):

☐ Minor ☐ Moderate ☐ Severe

Describe:_____

_____

_____

7. **Safety and Regulatory Requirements – Describe all applicable requirements:**_____

_____

_____

_____

_____

_____

8. **Other Requirements/Requests:**_____

_____

_____

_____

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_____

_____

Packaging Requirements are defined and recorded on SOP-148K, Project Packaging Requirements.

Attach additional documentation as necessary to fully define design inputs.

Reviewed and Approved By:_____ **Date:**_____

Authorized Customer Signature

Reviewed and Approved By:_____ **Date:**_____

BAW Project Manager Signature