SOP Title: BCA Protein Assay		
Document ID: 30009	Version	4.0
Page 1 of 18	Supersedes	3.0
Effective Date: 27Sep21		

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1. PURPOSE

1.1. The purpose of this procedure is to detect and quantitate total protein within a sample using the bicinchoninic acid (BCA) colorimetric assay.

2. SCOPE

2.1. This procedure applies to measuring total protein within HPV Virus-like particles (VLP) or biological samples.

3. REFERENCES

3.1. F.E. Grubbs, “Procedures for Detecting Outlying Observations in Samples” Technometrics 11:1 pp 1-21 (1969)

3.2. Qualification Report (YT16-130-01) for QC1 & QC2 (Developed in-house)

3.3. 10009: General Record Review

3.4. 15000: Waste Disposal at the Advanced Technology Research Facility

3.5. 26000: Biosafety Cabinet (BSC) Use and Maintenance

3.6. 26003: Use and Maintenance of a Molecular Devices Plate Reader

3.7. 26005: Use and Maintenance of a 2-8°C Refrigerator

3.8. 26009: Use and Maintenance of Pipettes

3.9. 26014: Use and Maintenance of a Laboratory Convection Incubators

3.10. 26020: Use and Maintenance of a Microplate Shaker

4. RESPONSIBILITIES

4.1. The Research Associate, hereafter referred to as Analyst, is responsible for reviewing and following this procedure, and documenting assay information.

4.2. The Scientific Manager or designee is responsible for training personnel in this procedure and reviewing associated documentation.

4.3. The Quality Assurance Specialist is responsible for quality oversight and approval of this procedure.

4.4. Trained personnel perform assay record review per "10009: General Record Review."

5. DEFINITIONS

Term	Definition
Abs	Absolute Value
Ave	Average Value
BCA	Bicinchoninic acid
BSA	Bovine Serum Albumin
CI	Confidence Interval
Conc	Concentration
CV	Coefficient of Variation (Percent)
FIO	For Information Only
ID	Identification
OD	Optical Density
RT	Room Temperature
WR	Working Reagent

6. REAGENTS, MATERIALS, AND EQUIPMENT

6.1. Reagents

6.1.1. BSA Standard, 2 mg/mL Concentration, 10 x 1 mL Ampoules (VWR, Cat # PI-23209 or equivalent)

6.1.2. BSA_QC1, Quality Control #1 (Developed in-house)

6.1.3. BSA_QC2, Quality Control #2 (Developed in-house)

6.1.4. 1X Dulbecco's PBS (DPBS) (Life Technologies, Cat # 14190-235 or equivalent)

6.1.5. Kit, Pierce BCA Protein Assay (VWR, Cat # PI23225 or PI23227)

6.2. Consumables

6.2.1. Plate, 96-well, Flat Bottom, Tissue Culture Plate (Thomas Scientific, Cat # 6906A07 or equivalent)

6.2.2. Plate Sealers, Clear (Thomas Scientific, Cat # 6980A01 or equivalent)

6.2.3. Reagent Reservoir (Corning, Cat # 4870 or equivalent)

6.2.4. Pipette Tips

6.2.5. Serological Pipettes (Ranging from 1 mL to 50 mL)

6.2.6. 1.5 mL Tubes, Microcentrifuge, Screw top (VWR, Cat # 10025-726 or equivalent)

6.2.7. 1.2 mL Tubes, Polypropylene, Cluster (VWR, Cat # 29442-612 or equivalent)

6.3. Equipment

6.3.1. Ampule Snapper/Breaker/Collar, Disposable (VWR, Cat # 66009-125, or equivalent)

6.3.2. Class II Biosafety Cabinet (BSC)

6.3.3. Convection Oven

6.3.4. Microplate Shaker

6.3.5. Microplate Reader (Molecular Devices M5 or equivalent)

6.3.6. Pipettes (Rainin)

6.3.7. Serologic Pipettor

7. HEALTH AND SAFETY CONSIDERATIONS

7.1. Proper safety precautions should be taken while working in a laboratory setting. This includes, but is not limited to, proper protective equipment such as lab coats, safety glasses, closed-toe shoes, and non-latex gloves.

7.2. When possible, needle-resistant gloves or disposable ampule snapper should be used when breaking open the BSA ampule and disposed of in a sharp's container.

7.3. Refer to the respective Safety Data Sheet (SDS) when working with any chemicals.

7.4. Refer to "15000: Waste Disposal at the Advanced Technology Research Facility," for waste disposal processes.

8. PROCEDURE PRINCIPLES

8.1. BCA Protein Assay is used to determine total protein concentration of an unknown sample.

8.2. Cu^{+2} is reduced to Cu^{+1} in the presence of protein when in an alkaline medium and is chelated to BCA, leading to absorbency at a wavelength of 562 nm and demonstrating linear correlation to protein values.

8.3. A known BSA standard curve is used to confirm protein concentrations and to calculate the unknown sample's protein concentration.

8.4. All work should be performed inside a BSC.

8.5. Process relevant information is recorded on "30009-01: BCA Data Capture Form."

8.6. Every BCA plate layout will include: BSA Standards (serially diluted into a Standard Curve), two positive Quality Control samples (one high OD and one low OD but each falling within the BSA Standard Curve range), and a reagent Blank; each tested in triplicate (see Figure 1 for plate layout).

9. PROCEDURE

9.1. Allow Laboratory Convection Incubator to reach temperature, 37 ± 2°C, per "26014: Use and Maintenance of a Laboratory Convection Incubators."

9.2. Thaw sample(s) at room temperature (RT) prior to use for at least 20 minutes, until fully thawed.

9.3. Label skirt/face of each 96-Flat Bottom plate with Plate Number, Data Reference/Assay Tracking Number, Analyst Initials, and Date. See Attachment 1: 96-Well Plate Skirt Label to properly label plate.

9.4. Standard Curve Preparation

9.4.1. Prepare nine dilution tubes and label each tube with vial letter (see Table 1) (may use cluster tubes if desired).

9.4.2. Prepare standard curve dilutions in DPBS.

9.4.2.1. Mix vial of BSA Standard by inversion, then tap liquid from lid to bottom of vial before opening ampule.

9.4.2.2. Carefully open an ampule of the BSA standard. Use needle-resistant gloves, or use an ampule snapper, to break lid of ampule on the line etched around top of vial neck.

Note: Dispose of glass top in a plastic sharps container.

9.4.2.3. Prepare BSA standard curve dilutions per Table 1.

Table 1: BSA Standard Curve Dilutions

Vial	Volume of DPBS (µL)	Volume and Source of Stock (µL)	Final BSA Concentration (µg/mL)
A	0	300 of Stock	2000
B	125	375 of Stock	1500
C	325	325 of Stock	1000
D	175	175 of Vial B Dilution	750
E	325	325 of Vial C Dilution	500
F	325	325 of Vial E Dilution	250
G	325	325 of Vial F Dilution	125
H	400	100 of vial G Dilution	25
I	400	0	0 (Blank)

9.5. Sample Preparation

9.5.1. Dilute each sample so the expected protein concentration falls within the standard curve.

9.5.1.1. Three separate dilution factors will be prepared for each sample.

9.5.1.2. A minimum of 100 µL total volume will be required for each sample Dilution Factor, as each will be plated in triplicate.

9.5.1.3. Initial sample dilutions are recommended in Table 2 but may be adjusted based on the expected protein concentration.

Table 2: Recommended Initial Sample Dilutions

Description	Starting Dilution Factor	Sample Volume	DPBS
Dilution 1	1:2	100 µL	100 µL
Dilution 2	1:4	100 µL of Dilution 1	100 µL
Dilution 3	1:8	100 µL of Dilution 2	100 µL

9.5.2. Add 25 µL of Standards, BSA_QC1, BSA_QC2, Blanks, and Samples to the plate in triplicate. Refer to Attachment 2 for plate layout.

Note: Unused sample wells remain empty throughout procedure.

9.6. Preparation and Addition of Working Reagent (WR)

Note: A volume of 200 µL of WR is required per well used in assay; including standards and controls. To test one 96-well plate, 25 mL total of WR is required.

9.6.1. Mix 50 parts BCA Reagent A with 1-part BCA Reagent B from kit to make WR.

9.6.1.1. For example, combine 25 mL of Reagent A with 500 µL Reagent B for a total of 25.5 mL WR.

Note: WR should be a clear green color when both reagents are mixed.

9.6.2. Add 200 µL of WR to all wells used, being careful not to touch pipette tip to liquid already present in plate.

9.7. Plate Incubation

9.7.1. Once all standards, controls, samples, and WR have been added to plate, cover plate with plate sealer and mix on a Plate Shaker at 250-350 rpm for approximately 30 seconds per “26020: Use and Maintenance of a Microplate Shaker.”

Figure 1. Plate Map for loading standards, controls, blank, and samples.

	1	2	3	4	5	6	7	8	9	10	11	12
A	2000 µg/mL			0 µg/mL (Blank)			BSA_QC1			BSA_QC2		
B	1500 µg/mL			Sample 1, Dilution 1			Sample 3, Dilution 1			Sample 5, Dilution 1		
C	1000 µg/mL			Sample 1, Dilution 2			Sample 3, Dilution 2			Sample 5, Dilution 2		
D	750 µg/mL			Sample 1, Dilution 3			Sample 3, Dilution 3			Sample 5, Dilution 3		
E	500 µg/mL			Sample 2, Dilution 1			Sample 4, Dilution 1			Sample 6, Dilution 1		
F	250 µg/mL			Sample 2, Dilution 2			Sample 4, Dilution 2			Sample 6, Dilution 2		
G	125 µg/mL			Sample 2, Dilution 3			Sample 4, Dilution 3			Sample 6, Dilution 3		
H	25 µg/mL			Sample 7, Dilution 1			Sample 7, Dilution 2			Sample 7, Dilution 3		

9.7.2. Incubate plate at 37 ± 2°C for 30 ± 5 minutes in Convection Incubator.

Note: Do not use CO_2 Incubator as this could introduce contamination to Incubator.

9.7.3. Remove plate from Convection Incubator and allow plate to equilibrate to RT for 5 ± 1 minutes.

9.8. Plate Reading

9.8.1. During RT incubation (step 9.7.2), turn on Plate Reader and open “BCA Template” Protocol file (.sprx) located under O:\HSL\HSL_Templates\BCA in SoftMax Pro.

9.8.2. Enter Sample IDs (HPV-Type, Sample Description, and Lot Number when applicable), Dilution Factors, and background information into template.

9.8.3. SoftMax Pro is connected to Plate Reader when instrument tab in the top left corner of the screen has a green checkmark over picture of the instrument.

9.8.4. Once RT incubation completed, remove plate sealer, place plate into Plate Reader tray with Plate Adapter in place.

9.8.5. Select corresponding assay plate under the template-specific Navigation Tree on the left of the screen, then select “Read” on the screen.

9.8.6. Name data file as follows:

“Data Reference/Assay Tracking Number_BCA_DDMMMYYAnalyst Initials” (L0001003_BCA_20MAY17ABC)

9.8.7. Save file as a data file (.sdax) in O:\HSL\Plate Reader\Raw Data Files\BCA.

10. SYSTEM SUITABILITY

10.1. BSA_QC1 and BSA_QC2 Controls Acceptance Criteria

10.1.1. Three replicates of each in-house developed control are run on every plate.

Note: Refer to corresponding notebook for specific acceptance criteria from the established Qualification Report (currently YT16-130-01) or discuss with Scientific Manager.

10.1.2. The BSA_QC1 and BSA_QC2 Controls must have a percent CV of ≤ 20%.

10.1.3. One well may be masked within the replicates if it does not meet percent CV criteria. See Attachment 3: Outlier Test: Grubb's Test for Triplicates for outlier assessment to indicate which Optical Density (OD) value between triplicates is masked for calculation.

10.2. **Blank Acceptance Criteria**

10.2.1. Three replicates of 1X DPBS Blank Control are run on every plate.

10.2.2. The Blank Control Average must have an average absorbance reading below the 25 µg/mL BSA standard. (See section 10.3)

Note: Up to one well may be masked if considered contaminated.

10.3. **2000 µg/mL and 25 µg/mL BSA Standard Curve Acceptance Criteria**

10.3.1. Three replicates of each 2000 µg/mL and 25 µg/mL BSA Standards are run on every plate.

10.3.1.1. 2000 µg/mL BSA Standard is also referred to as the **Top of the Standard Curve**.

10.3.1.2. 25 µg/mL BSA Standard is also referred to as the **Bottom of the Standard Curve**.

10.3.2. The percent CV for the two standard replicates of 2000 µg/mL and 25 µg/mL only must be ≤15 % for the data to be considered valid.

10.3.3. One well may be masked within this range if it does not meet the percent CV criteria. See Attachment 3: Outlier Test: Grubb's Test for Triplicates for outlier assessment to indicate which Optical Density (OD) value between triplicates is masked for calculation.

10.4. **Remaining BSA Standard Curve Acceptance Criteria**

10.4.1. Three replicates of 1500 µg/mL to 125 µg/mL BSA Standards are run on every plate.

10.4.2. The percent CV between the remaining standard replicates of 1500 µg/mL to 125 µg/mL must be ≤ 10% for the data to be considered valid.

10.4.3. One well may be masked within this range if it does not meet the percent CV criteria. See Attachment 3 for outlier assessment to indicate which Optical Density (OD) value between triplicates is masked for calculation.

10.5. **Standard Curve**

10.5.1. Only one full standard concentration (three wells) may be masked in the standard curve range.

10.5.2. If more than one standard needs to be masked, then the whole plate needs to be retested.

10.5.3. The same standard preparation may be used for the retest if made in the same day; otherwise, a new set of standards needs to be created.

10.5.4. If the standards fail system suitability on the retest, then a new set of standard dilutions will need to be prepared prior to testing a third time.

11. QUALITY CONTROL

11.1. Two positive control samples (BSA QC 1 and BSA QC 2) will be added to each plate in triplicate.

11.2. Document the QC ranges on 30009-01 and indicate whether the QC samples passed or failed.

11.3. Log the QC data in the BCA QC Trending file.

11.4. If either of the QC samples is out of range, then the whole plate is repeated. A new set of QC samples will be used on the retest.

11.5. If the same control fails on two subsequent runs, the control trending data is reviewed by the Scientific Manager and further testing guidance is provided by the Scientific Manager or designee.

12. DATA ANALYSIS

12.1. Sample Results

12.1.1. At least one of the Sample Dilutions tested must fall within the BCA Standard Curve at concentrations of 1500 µg/mL to 125 µg/mL for the results to be valid.

12.1.1.1. If not, repeat the Sample testing at a different set of dilutions, where the protein concentration for at least one of the sample dilutions falls within the standard curve.

12.1.2. The percent CV within the triplicates of each Sample Dilution must be ≤ 20% for the data to be considered valid.

12.1.2.1. If any triplicates have a percent CV of >20%, see Attachment 3 for outlier assessment to indicate which OD value between triplicates is masked for calculation.

12.1.3. If any of these criteria are not met, repeat the sample test.

12.1.4. Following Data Analysis, print data file and attach to 30009-01 form. De-select Audit Trail from Printer Preferences if not needed.

13. ATTACHMENTS

13.1. Attachment 1: 96-Well Plate Skirt Label

13.2. Attachment 2: Plate Layout

13.3. Attachment 3: Outlier Test: Grubb's Test for Triplicates

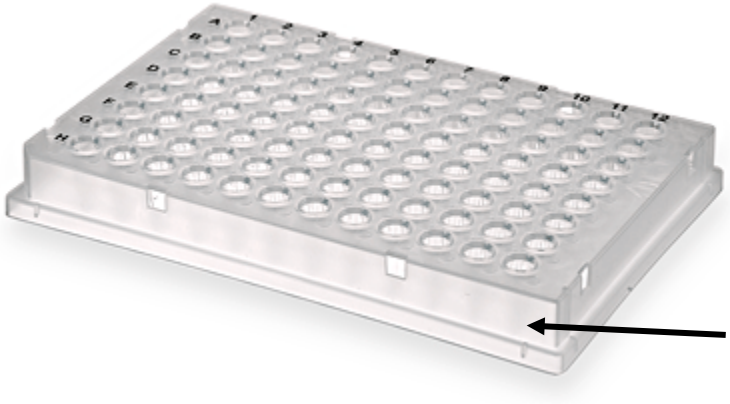
13.4. Attachment 4: 30009-01: BCA Data Capture Form

14. REVISION HISTORY

Version	Change	Reason
2.0	Update forms to include incubation times at 37C Tighten Standard Control %CV Ranges. Update Forms.	Need to tighten %CV Ranges to align assay with practices/results. General updates to clarify what information is expected.
3.0	1. Update to new SOP format. Forms now separate. 2. Minor grammar and formatting changes throughout document. 3. Removed HSL_GL_002, HSL_GL_003, HSL_GL_004, HSL_GL_005, HSL_GL_006, HSL_GL_007, HSL_GL_008, HSL_GL_009, HSL_GL_010,	1. Consistency between procedures. Ease of use. 2. Clarification. 3. Not referenced in procedure. New reference for procedure.

	HSL_EQ_002 from References section. Added reference to F.E. Grubbs publication. 4. Split Reagents, Equipment and Materials into three subsections. Added oven, plate shaker, plate reader, pipettes, pipette tips, reagent reservoir, serological pipettes and pipette. 5. Changed “Background” section to Procedure Principles in new format. Added reference that all work performed in BSC, process related info recorded on form. 6. Removed ATRF, FME, SOP and added BCA and ID to definitions section. 7. Section 9, added step to label plate. 8. Deleted Note under Table 1. 9. Added sample thaw step in sample preparation section. 10. Added note that unused sample wells remain empty, and not to use CO2 incubator in WR section. 11. Added outlier calculation step to section 10 and as Attachment 2. 12. Updated well masking for blanks in Section 10. 13. Added reference for where to find control range. 14. Rephrased section 11.	4. Consistency between procedures, clarification. 5. Consistency between procedures, clarification. 6. ATRF referenced in Scope, FME, SOP not referenced in procedure. BCA and ID referenced in procedure. 7. Reflect current practice. 8. Information captured in later step. 9. Reflect current practice. 10. Clarification. 11. Update to process. 12. Update to process. 13. Clarification. 14. Clarification.
4.0	1. Updated Reference section 2. Updated System Suitability, Quality Control, and Data Analysis Section	1. Consistency between procedures, clarification. 2. Clarification and reflect GCLP practice

Attachment 1: 96-Well Plate Skirt Label



Label in this area (plate skirt/face)

Attachment 2: Plate Layout

	1	2	3	4	5	6	7	8	9	10	11	12
A	2000 µg/mL			0 µg/mL (Blank)			BSA_QC1			BSA_QC2		
B	1500 µg/mL			Sample 1, Dilution 1			Sample 3, Dilution 1			Sample 5, Dilution 1		
C	1000 µg/mL			Sample 1, Dilution 2			Sample 3, Dilution 2			Sample 5, Dilution 2		
D	750 µg/mL			Sample 1, Dilution 3			Sample 3, Dilution 3			Sample 5, Dilution 3		
E	500 µg/mL			Sample 2, Dilution 1			Sample 4, Dilution 1			Sample 6, Dilution 1		
F	250 µg/mL			Sample 2, Dilution 2			Sample 4, Dilution 2			Sample 6, Dilution 2		
G	125 µg/mL			Sample 2, Dilution 3			Sample 4, Dilution 3			Sample 6, Dilution 3		
H	25 µg/mL			Sample 7, Dilution 1			Sample 7, Dilution 2			Sample 7, Dilution 3		

Attachment 3: Outlier Test: Grubb's Test for Triplicates (Standard Deviation Method)

1. Rank the three values from lowest to highest: X1, X2, X3.
2. Calculate the Mean (M) and Standard Deviation (SD).
   a. $M = (X1 + X2 + X3) / 3$
   b. $SD = \sqrt{((X1-M)^2 + (X2-M)^2 + (X3-M)^2) / 3)}$
3. Calculate the Grubb's Test (GT) value using calculation below if the HIGHEST value (X3) is the suspected outlier.

   $GT = (X3-M) / SD$
4. Calculate the GT value using calculation below if the LOWEST value (X1) is the suspected outlier.

   $GT = (M-X1) / SD$
5. If the GT is GREATER THAN the value in the table below, the suspected value IS an outlier.

N # replicates	95% CI	97.5% CI	99% CI
3	1.15	1.15	1.15

Attachment 4: 30009-01: BCA Data Capture Form

Frederick National Laboratory for Cancer Research sponsored by the National Cancer Institute		HPV Serology Laboratory Standard Operating Procedure Form	
Form Title: BCA Data Capture Form			
Document ID: 30009-01		Version:	4.0
Associated SOP: 30009		Effective Date:	27Sep21
Supersedes Version:	3.0	**Page 1 of 4**	

Equipment

Equipment Description	Equipment ID	Calibration Due Date
BSC	□ HSL_007 □ HSL_008 □ Other:	
Convection Oven	□ HSL_025 □ Other:	
Microplate Shaker	□ HSL_030 □ HSL_031 □ Other: □ Other:	
Microplate Reader	□ HSL_018 □ Other:	
Pipette: µL	PIP_	
□ N/A Pipette: µL	PIP_	
□ N/A Pipette: µL	PIP_	
□ N/A Pipette: µL	PIP_	
□ N/A Pipette: µL	PIP_	

Reagents

Reagent	Lot Number	Expiration Date
DPBS		
BCA Kit		□ N/A
BSA Standard, 2 mg/mL		□ N/A
BSA_QC1		□ N/A
BSA_QC2		□ N/A

Sample Identification □ N/A (No samples prepared)

Sample Number	HPV Type	Sample Description	Data Reference/Unique Identifier
example	*HPV-16*	*Pooled fractions 3-5, T225*	*L0001001*
1 □ N/A			
2 □ N/A			
3 □ N/A			
4 □ N/A			
5 □ N/A			
6 □ N/A			
7 □ N/A			

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Document ID: 30009-01		Version:	4.0
Associated SOP: 30009		Effective Date:	27Sep21
Supersedes Version:	3.0	**Page 2 of 4**	

Sample Preparation ☐ N/A (No samples prepared)

Sample Number	Starting Dilution Factor	Sample Volume (µL)	DPBS Volume (µL)
1 ☐ N/A	1.		
	2.	µL of Dilution 1	
	3.	µL of Dilution 2	
2 ☐ N/A	1.		
	2.	µL of Dilution 1	
	3.	µL of Dilution 2	
3 ☐ N/A	1.		
	2.	µL of Dilution 1	
	3.	µL of Dilution 2	
4 ☐ N/A	1.		
	2.	µL of Dilution 1	
	3.	µL of Dilution 2	
5 ☐ N/A	1.		
	2.	µL of Dilution 1	
	3.	µL of Dilution 2	
6 ☐ N/A	1.		
	2.	µL of Dilution 1	
	3.	µL of Dilution 2	
7 ☐ N/A	1.		
	2.	µL of Dilution 1	
	3.	µL of Dilution 2	

Incubation Times

Condition	Start Time	End Time	Total Time (Min)
37°C 30±5 minutes			
RT Equilibration 5±1 minutes		Read Start Time:	

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Frederick National Laboratory for Cancer Research
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HPV Serology Laboratory
Standard Operating Procedure
Form

Form Title: BCA Data Capture Form

Document ID: 30009-01		Version:	4.0
Associated SOP: 30009		Effective Date:	27Sep21
Supersedes Version:	3.0	**Page 3 of 4**	

Data File Name: _____

System Suitability Results

Curve	Range	Pass, Fail
2000 µg/mL	% CV ≤ 15%	☐ Pass ☐ Fail
1500 µg/mL	% CV ≤ 10%	☐ Pass ☐ Fail
1000 µg/mL	% CV ≤ 10%	☐ Pass ☐ Fail
750 µg/mL	% CV ≤ 10%	☐ Pass ☐ Fail
500 µg/mL	% CV ≤10%	☐ Pass ☐ Fail
250 µg/mL	% CV ≤ 10%	☐ Pass ☐ Fail
125 µg/mL	% CV ≤ 10%	☐ Pass ☐ Fail
25 µg/mL	% CV ≤ 15%	☐ Pass ☐ Fail
0 µg/mL (Blank)	Abs Value < 25 µg/mL STD	☐ Pass ☐ Fail

QC Description	Range	Reported Result	Pass, Fail
BSA_QC1	% CV ≤ 20%		☐ Pass ☐ Fail
	Conc. Range: (µg/mL)		☐ Pass ☐ Fail
BSA_QC2	% CV ≤ 20%		☐ Pass ☐ Fail
	Conc. Range: (µg/mL)		☐ Pass ☐ Fail

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Associated SOP: 30009		Effective Date:	27Sep21
Supersedes Version:	3.0	**Page 4 of 4**	

Sample Results ☐ N/A (No samples prepared)

Sample Number	Reported Result (µg/mL) *	% CV of Reported Results *(Range ≤ 20%)*	Pass, Fail, FIO, N/A
1 ☐ N/A			☐ Pass ☐ Fail ☐ FIO ☐ N/A
2 ☐ N/A			☐ Pass ☐ Fail ☐ FIO ☐ N/A
3 ☐ N/A			☐ Pass ☐ Fail ☐ FIO ☐ N/A
4 ☐ N/A			☐ Pass ☐ Fail ☐ FIO ☐ N/A
5 ☐ N/A			☐ Pass ☐ Fail ☐ FIO ☐ N/A
6 ☐ N/A			☐ Pass ☐ Fail ☐ FIO ☐ N/A
7 ☐ N/A			☐ Pass ☐ Fail ☐ FIO ☐ N/A
For ALL Samples tested which fall within Range of Std Curve: do they all pass % CV?			☐ Pass ☐ Fail ☐ FIO ☐ N/A

***only for values within range of curve, that pass % CV criteria**

Comments:

☐ N/A

Performed by/date:	
Reviewed by/date:	

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