

Appendix (A): Clinic Information

Please fill in the blanks below and use this as a Fax cover

Clinic Name		
Lab director's Name		
Operator Name		
E-mail		
Clinic's address		
Clinic's number	Tel)	Fax)
FREND Serial number	Setup → System View → Serial Number F10U	
AP Serial number	Backside of AP FAP	
Check in the box of the item that you installed in your clinic.	Select installed items	Appendix included in this FAX
	<input type="checkbox"/> Free T4	
	<input type="checkbox"/> PSA Plus	
	<input type="checkbox"/> Testosterone	
	<input type="checkbox"/> TSH	
	<input type="checkbox"/> Vitamin D	

Contact information

Address	22287 Mulholland Hwy, Calabasas CA 91302
FAX	818-348-9696
E-mail	nova-one@sbcglobal.net
Tel.	818-348-1543 Toll Free: 800-810-7488

Appendix (B): Verification of Reportable Range / Calibration

- It's optional to verify the reportable range and calibration.

Materials to be prepared

1. FRENTM Linearity Kit from NanoEnTek
2. FRENTM Cartridges (Reagents), FRENTM System and companion devices if required.
3. Pipette (35µL) and tips

(Attach FRENTM Linearity Kit Card Here)

Assay name	Cartridge LOT#	Exp. Date (MM/DD/YY)
		/ /

Date of starting test (MM/DD/YY): _____

Verification of Reportable Range

	Vial A	Vial C	Vial E
Test Result			
Is it same as indicated? (Y/N)	Y / N	Y / N	Y / N

Assay Name	Reportable Range	Result Reporting
Free T4	0.4 – 6.0 ng/dL	< 0.4 ng/dL > 6.0 ng/dL
PSA Plus	0.08 – 25 ng/mL	< 0.08 ng/mL > 25 ng/mL
Testosterone	20 – 1500 ng/dL	< 20 ng/dL > 1500 ng/dL
TSH	0.06 – 25 mIU/L	< 0.06 mIU/L > 25 mIU/L
Vitamin D	13.0 – 96.0 ng/mL	< 13.0 ng/mL > 96.0 ng/mL

Calibration Verification

Repeat	Vial B	Vial C	Vial D
#1			
#2			
#3			

* Repeat if the result is out of range.

* Copy additional pages as needed in case for more items or if you have another FRENTM System.

* Please, scan this file as PDF or Image and send to nova-one@sbcglobal.net or fax this document to **818-348-9696**

Appendix (C): Verification of Accuracy / Precision

Free T4

Cartridge Lot#: _____ / Expiration Date: _____

External QC range		
	Mean(ng/dL)	Expected Ranges
Level 1	1.11	0.29 ~ 1.63
Level 2	1.85	1.22 ~ 2.48
LOT #	2008122A, 2008123A	
Exp. Date	2023-10-31	

* Specifications vary by Lot#. For lot-specific values, please visit CLINIQA's website (www.cliniqa.com), click the "Document Search" tab, enter your Lot number, and you will find the document containing the correct values.

Day 1 Perform 5 times Date ()	Level 1 Comment:					
Day 2 Perform 5 times Date ()	Level 2 Comment:					
Day 2 Perform 5 times Date ()	Level 1 Comment:					
Day 2 Perform 5 times Date ()	Level 2 Comment:					

Please, scan this file as PDF or Image and send to nova-one@sbcglobal.net or fax this document to **818-348-9696**

Appendix (C): Verification of Accuracy / Precision

PSA Plus

Cartridge Lot#: _____ / Expiration Date: _____

External QC range		
	Mean(ng/mL)	Expected Ranges
Level 1	1.70	0.98 ~ 2.42
Level 2	14.95	9.55 ~ 20.35
LOT #	2008122A, 2008123A	
Exp. Date	2023-10-31	

* Specifications vary by Lot#. For lot-specific values, please visit CLINIQA's website (www.cliniqa.com), click the "Document Search" tab, enter your Lot number, and you will find the document containing the correct values.

Day 1 Perform 5 times Date ()	Level 1 Comment:					
Day 2 Perform 5 times Date ()	Level 2 Comment:					
Day 1 Perform 5 times Date ()	Level 1 Comment:					
Day 2 Perform 5 times Date ()	Level 2 Comment:					

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Appendix (C): Verification of Accuracy / Precision

Testosterone

Cartridge Lot#: _____ / Expiration Date: _____

External QC range		
	Mean(ng/dL)	Expected Ranges
Level 1	193.45	86.08 ~ 300.83
Level 2	947.56	585.36 ~ 1309.77
LOT #	2008122A, 2008123A	
Exp. Date	2023-10-31	

* Specifications vary by Lot#. For lot-specific values, please visit CLINIQA's website (www.cliniqa.com), click the "Document Search" tab, enter your Lot number, and you will find the document containing the correct values.

Day 1 Perform 5 times Date ()	Level 1 Comment:					
Day 2 Perform 5 times Date ()	Level 2 Comment:					
Day 2 Perform 5 times Date ()	Level 1 Comment:					
Day 2 Perform 5 times Date ()	Level 2 Comment:					

Please, scan this file as PDF or Image and send to nova-one@sbcglobal.net or fax this document to **818-348-9696**

Appendix (C): Verification of Accuracy / Precision

TSH

Cartridge Lot#: _____ / Expiration Date: _____

External QC range		
	Mean(mIU/L)	Expected Ranges
Level 1	1.10	0.63 ~ 1.57
Level 2	12.54	8.66 ~ 16.42
LOT #	2008122A, 2008123A	
Exp. Date	2023-10-31	

* Specifications vary by Lot#. For lot-specific values, please visit CLINIQA's website (www.cliniga.com), click the "Document Search" tab, enter your Lot number, and you will find the document containing the correct values.

Day 1 Perform 5 times Date ()	Level 1 Comment:						
Day 2 Perform 5 times Date ()	Level 2 Comment:						
Day 2 Perform 5 times Date ()	Level 1 Comment:						
Day 2 Perform 5 times Date ()	Level 2 Comment:						

Please, scan this file as PDF or Image and send to nova-one@sbcglobal.net or fax this document to **818-348-9696**

Appendix (C): Verification of Accuracy / Precision

Vitamin D

Cartridge Lot#: _____ / Expiration Date: _____

External QC range		
	Mean(ng/mL)	Expected Ranges
Level 1	40.01	20.61 ~ 59.41
Level 2	60.03	40.16 ~ 79.90
LOT #	1907082B, 1907083	
Exp. Date	2021-09-30	

* Specifications vary by Lot#. For lot-specific values, please visit CLINIQA's website (www.cliniqa.com), click the "Document Search" tab, enter your Lot number, and you will find the document containing the correct values.

Day 1 Perform 5 times Date ()	Level 1 Comment:					
Level 2 Comment:						
Day 2 Perform 5 times Date ()	Level 1 Comment:					
Level 2 Comment:						

Please, scan this file as PDF or Image and send to nova-one@sbcglobal.net or fax this document to 818-348-9696

Appendix (G): Quality Control (QC) Log – Free T4

Test item		Free T4			FREND™ Serial Number		F10U -		
Ex.QC Level 1 Lot #		2008122A			Ex. QC Expiration Date		2023-10-31		
Ex.QC Level 2 Lot #		2008123A							
Range	Level 1	Low	Mean	High	Level 2	Low	Mean	High	
		0.59	1.11	1.63		1.22	1.85	2.48	
Test Date (MM/DD/YY)		Cartridge LOT#	QC Cartridge (Pass / Fail)	Level 1	Level 2	Tech/ Date			
/	/		Pass / Fail						
/	/		Pass / Fail						
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If a new lot number of external QC solution is opened, use new format and attach validation results to this Log. Repeat if the result is out of range.

Laboratory Director

Date

Appendix (G): Quality Control (QC) Log – PSA Plus

Test item		PSA Plus			FREND™ Serial Number		F10U -		
Ex.QC Level 1 Lot #		2008122A			Ex. QC Expiration Date		2023-10-31		
Ex.QC Level 2 Lot #		2008123A							
Range	Level 1	Low	Mean	High	Level 2	Low	Mean	High	
		0.98	1.70	2.42		9.55	14.95	20.35	
Test Date (MM/DD/YY)		Cartridge LOT#	QC Cartridge (Pass / Fail)	Level 1		Level 2		Tech/Date	
/	/		Pass / Fail						
/	/		Pass / Fail						
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If a new lot number of external QC solution is opened, use new format and attach validation results to this Log. Repeat if the result is out of range.

Laboratory Director

Date

Appendix (G): Quality Control (QC) Log – Testosterone

Test item		Testosterone			FREND™ Serial Number		F10U -		
Ex.QC Level 1 Lot #		2008122A			Ex. QC Expiration Date		2023-10-31		
Ex.QC Level 2 Lot #		2008123A							
Range	Level 1	Low	Mean	High	Level 2	Low	Mean	High	
		86.08	193.45	300.83		585.36	947.56	1309.77	
Test Date (MM/DD/YY)		Cartridge LOT#	QC Cartridge (Pass / Fail)	Level 1	Level 2	Tech/ Date			
/ /			Pass / Fail						
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If a new lot number of external QC solution is opened, use new format and attach validation results to this Log. Repeat if the result is out of range.

Laboratory Director **Date**

Appendix (G): Quality Control (QC) Log – TSH

Test item		TSH			FREND™ Serial Number	F10U -		
Ex.QC Level 1 Lot #		2008122A			Ex. QC Expiration Date	2023-10-31		
Ex.QC Level 2 Lot #		2008123A						
Range	Level 1	Low	Mean	High	Level 2	Low	Mean	High
		0.63	1.10	1.57		8.66	12.54	16.42
Test Date (MM/DD/YY)		Cartridge LOT#	QC Cartridge (Pass / Fail)	Level 1	Level 2	Tech/Date		
/	/		Pass / Fail					
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If a new lot number of external QC solution is opened, use new format and attach validation results to this Log. Repeat if the result is out of range.

Laboratory Director

Date

Appendix (G): Quality Control (QC) Log – Vitamin D

Test item		Vitamin D			FREND™ Serial Number		F10U -		
Ex. QC Level 1 Lot #		1907082B			Ex. QC Expiration Date		2021-09-30		
Ex. QC Level 2 Lot #		1907083							
Range	Level 1	Low	Mean	High	Level 2	Low	Mean	High	
		20.61	40.01	59.41		40.16	60.03	79.90	
Test Date (MM/DD/YY)	Cartridge LOT#	QC Cartridge (Pass / Fail)		Level 1	Level 2	Tech/ Date			
/ /		Pass / Fail							
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If a new lot number of external QC solution is opened, use new format and attach validation results to this Log. Repeat if the result is out of range.

Laboratory Director

Date

Appendix (H): External QC New Lot Number Verification

Perform this verification BEFORE you run out of the current control lot number. Before putting a new lot of control materials into use, verify that the new control performs as expected by parallel testing with the current lot number. All lot results should be within range each day. Run the new control several times (**5 times for CLIA and COLA inspection**), preferably on more than one day and using more than one operator. If the new control results are within range, you have verified the new control lot and can put it into use when the current QC lot is depleted. You will want to take action to determine why the control is not performing as expected when the new control results are outside of the range. Copy additional pages in case you needed.

Level	Exp. Date (MM/DD/YY)	LOT #	Mean	Expected Range			
Current QC lot	Level 1	/ / /		-			
	Level 2	/ / /		-			
New QC lot	Level 1	/ / /		-			
	Level 2	/ / /		-			
Test item & Cartridge lot #	Date	Run	Level 1 result	Level 2 result	Tested by	Verified (Y/N)	Reviewed by
Current QC lot	/ / /	1					
	/ / /	2					
	/ / /	3					
	/ / /	4					
	/ / /	5					
	/ / /	6					
	/ / /	7					
	/ / /	8					
	/ / /	9					
	/ / /	10					
New QC lot	/ / /	1					
	/ / /	2					
	/ / /	3					
	/ / /	4					
	/ / /	5					
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	/ / /	10					

***5 times for CLIA and COLA inspection**

*Please, scan this file as PDF or Image and send to nova-one@sbcglobal.net or fax this document to **818-348-9696**

Appendix (O): Maintenance Log

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	3	3	3	1				
Daily																																							
Wipe dust on FREND™ System																																							
Power-on FREND™ System & View Screen																																							
Record Temperature / Humidity																																							
Monthly																																							
USB Data Back-up																																							
External QC																																							
As needed																																							
External QC																																							
New shipment, New lot																																							
Internal procedural control Error Log																																							

Reviewed by: _____ Date: _____