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**	
Check in the box of the item that you installed in your clinic.	**Select installed items**	**Appendix included in this FAX**
	☐ **Free T4**	
	☐ **PSA**	
	☐ **Testosterone**	
	☐ **TSH**	
	☐ **25-Hydroxy Vitamin D**	

Contact information

Address	220 Bear Hill Road, STE 102. Waltham, MA 02451
E-mail	support@nanoentek.com
FAX	(781) 790-5649
Tel.	781-472-2558

Appendix (B): Verification of Reportable Range / Calibration

Materials to use:

1. FREND™ Linearity Kit from Nova-One Diagnostics (Nova-One.org)
2. FREND™ Cartridges (fT4 Reagents), FREND™ System and Auto Processor (AP)
3. Pipette and tips: 70 µL placed in Pretreatment Tube, place fT4 cartridge and Pretreatment tube in AP. When completed, place cartridge from AP into FREND. Use LIN mode.

Assay Name	Cartridge LOT#	Exp. Date (MM/DD/YR)
fT4		/ /

Verification of Reportable Range

Nova-One Lot #: 6210A21002

Date of testing (MM/DD/YR): **/ /**

Calibration Verification Results

(Unit: ng/dL)

	Vial - **1**	Vial - **5**	
Range	<0.40 – **<0.40** – 1.21	2.47 – **4.11** – 5.75	
Run #1			
Run #2			
Run #3			
	Vial - 2	**Vial - 3**	**Vial - 4**
Range	1.26 – **2.10** – 2.94	1.85 – **3.09** – 4.33	2.20 – **3.66** – 5.12
Run #1			
Run #2			
Run #3			

* Run All Vials in Triplicate on same day
* Repeat if the result is out of range.
* Copy additional pages as needed in case for more items or if you have another FREND™ System.
* Please, scan this file as PDF or Image and send to **support@nanoentek.com** or fax this document to **(781) 790-5649**

Appendix (B): Verification of Reportable Range / Calibration

Materials to use:

1. FREND™ Linearity Kit from Nova-One Diagnostics (Nova-One.org)
2. FREND™ Cartridges (PSA Reagents), FREND™ System
3. Pipette and tips: 35 µL placed directly onto PSA Cartridge. Place PSA cartridge on FREND. Use LIN mode.

Assay Name	Cartridge LOT#	Exp. Date (MM/DD/YR)
PSA		/ /

Verification of Reportable Range

Nova-One Lot #: 6210A21002

Date of testing (MM/DD/YR): **/ /**

Calibration Verification Results

(Unit: ng/mL)

	Vial - **1**	Vial - **5**
Range	0.09 – **0.23** – 0.38	**>25.00**
Run #1		
Run #2		
Run #3		

	Vial - **2**	Vial - **3**	Vial - **4**
Range	3.84 – **6.40** – 8.96	7.06 – **11.77** –16.48	13.04 – **21.73** –>25.00
Run #1			
Run #2			
Run #3			

* Run All Vials in Triplicate on same day
* Repeat if the result is out of range.
* Copy additional pages as needed in case for more items or if you have another FREND™ System.
* Please, scan this file as PDF or Image and send to **support@nanoentek.com** or fax this document to **(781) 790-5649**

Appendix (B): Verification of Reportable Range / Calibration

Materials to use:

1. FREND™ Linearity Kit from Nova-One Diagnostics (Nova-One.org)
2. FREND™ Cartridges (Testosterone Reagents), FREND™ System and Auto Processor (AP)
3. Pipette and tips: 70 µL placed in Pretreatment Tube, place Testosterone cartridge and Pretreatment tube in AP. When completed, place cartridge from AP into FREND. Use LIN mode.

Assay Name	Cartridge LOT#	Exp. Date (MM/DD/YR)
Testosterone		/ /

Verification of Reportable Range

Nova-One Lot #: 6210A21002

Date of testing (MM/DD/YR): **/ /**

Calibration Verification Results

(Unit: ng/dL)

	Vial - **1**	Vial - **5**
Range	<20.00 – **<20.00** – 33.02	683.3 – **1139** – >1500
Run #1		
Run #2		
Run #3		

	Vial - **2**	Vial – **3**	Vial - **4**
Range	136.7 – **227.8** – 318.9	253.9 – **423.1** – 592.3	468.3 – **780.5** – 1093
Run #1			
Run #2			
Run #3			

* Run All Vials in Triplicate on same day
* Repeat if the result is out of range.
* Copy additional pages as needed in case for more items or if you have another FREND™ System.
* Please, scan this file as PDF or Image and send to **support@nanoentek.com** or fax this document to **(781) 790-5649**

Appendix (B): Verification of Reportable Range / Calibration

Materials to use:

1. FREND™ Linearity Kit from Nova-One Diagnostics (Nova-One.org)
2. FREND™ Cartridges (TSH Reagents), FREND™ System
3. Pipette and tips: 35 µL placed directly onto TSH Cartridge. Place TSH cartridge on FREND. Use LIN mode.

Assay Name	Cartridge LOT#	Exp. Date (MM/DD/YR)
TSH		/ /

Verification of Reportable Range

Nova-One Lot #: 6210A21002

Date of testing (MM/DD/YR): **/ /**

Calibration Verification Results

(Unit: mIU/L)

	Vial - 1	Vial - 5	
Range	<0.06 – **<0.06** – 0.26	22.75 – **>25.00** – >25.00	
Run #1			
Run #2			
Run #3			
	Vial - 2	**Vial – 3**	**Vial - 4**
Range	3.36 – **5.59** – 7.83	6.09 – **10.14** –14.20	10.09 – **16.81** – 23.54
Run #1			
Run #2			
Run #3			

* Run All Vials in Triplicate on same day
* Repeat if the result is out of range.
* Copy additional pages as needed in case for more items or if you have another FREND™ System.
* Please, scan this file as PDF or Image and send to **support@nanoentek.com** or fax this document to **(781) 790-5649**

Appendix (B): Verification of Reportable Range / Calibration

Materials to use:

1. FREND™ Linearity Kit from Nova-One Diagnostics (Nova-One.org)
2. FREND™ Cartridges (Vitamin D Reagents), FREND™ System and Auto Processor (AP)
3. Pipette and tips: 35 µL placed into dilution buffer and mixed it. 70 µL from the mixture on the pretreatment tube, place the Vitamin D cartridge and pretreatment tube in AP. When complete, place the cartridge from AP into FREND. Use LIN mode

Assay Name	Cartridge LOT#	Exp. Date (MM/DD/YR)
Vitamin D		/ /

Verification of Reportable Range

Nova-One Lot #: 6210A21002

Date of testing (MM/DD/YR): **/ /**

Calibration Verification Results

(Unit: ng/mL)

	Vial - 1	Vial - 5	
Range	<13.00 – **<13.00** – 23.24	93.80 – **>96.00** – >96.00	
Run #1			
Run #2			
Run #3			
	Vial - 2	**Vial – 3**	**Vial - 4**
Range	<13.00 – **26.35** – 42.30	27.30 – **45.50** – 63.70	54.02 – **90.04** – >96.00
Run #1			
Run #2			
Run #3			

* Run All Vials in Triplicate on same day
* Repeat if the result is out of range.
* Copy additional pages as needed in case for more items or if you have another FREND™ System.
* Please, scan this file as PDF or Image and send to **support@nanoentek.com** or fax this document to **(781) 790-5649**

Appendix (C): Verification of Accuracy / Precision

Free T4

Cartridge Lot#:_____ / Expiration Date:_____

External QC range

	Mean	Expected Ranges
Level 1	**0.97**	0.53 – 1.40
Level 2	**1.93**	1.02 – 2.84
LOT #	6361A23002, 6362A23002	
Exp. Date	2025-11-30	

* Specifications vary by Lot#. For lot-specific values, please visit NovaOne's website (nova-one.org).

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 **support@nanoentek.com** or fax this document to **(781) 790-5649**

Appendix (C): Verification of Accuracy / Precision

PSA

Cartridge Lot#:_____ / Expiration Date:_____

External QC range

	Mean	Expected Ranges
Level 1	**2.68**	1.57 – 3.78
Level 2	**22.33**	14.01 – >25.00
LOT #	6361A23002, 6362A23002	
Exp. Date	2025-11-30	

* Specifications vary by Lot#. For lot-specific values, please visit NovaOne's website (nova-one.org).

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 **support@nanoentek.com** or fax this document to **(781) 790-5649**

Appendix (C): Verification of Accuracy / Precision

Testosterone

Cartridge Lot#:_____ / Expiration Date:_____

External QC range

	Mean	Expected Ranges
Level 1	**393.4**	221.0 – 565.9
Level 2	**1307**	819.1 – >1500
LOT #	6361A23002, 6362A23002	
Exp. Date	2025-11-30	

* Specifications vary by Lot#. For lot-specific values, please visit NovaOne's website (nova-one.org).

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 **support@nanoentek.com** or fax this document to **(781) 790-5649**

Appendix (C): Verification of Accuracy / Precision

TSH

Cartridge Lot#:_____ / Expiration Date:_____

External QC range

	Mean	Expected Ranges
Level 1	**2.01**	1.20 – 2.81
Level 2	**17.82**	11.18 – 24.46
LOT #	6361A23002, 6362A23002	
Exp. Date	2025-11-30	

* Specifications vary by Lot#. For lot-specific values, please visit NovaOne's website (nova-one.org).

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 **support@nanoentek.com** or fax this document to **(781) 790-5649**

Appendix (C): Verification of Accuracy / Precision

25-hydroxy vitamin D

Cartridge Lot#:_____ / Expiration Date:_____

External QC range

	Mean	Expected Ranges
Level 1	**40.89**	21.53 – 60.26
Level 2	**70.60**	44.11 – >96.00
LOT #	6361A23002, 6362A23002	
Exp. Date	2025-11-30	

* Specifications vary by Lot#. For lot-specific values, please visit NovaOne's website (nova-one.org).

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 **support@nanoentek.com** or fax this document to **(781) 790-5649**

Appendix (D): Split Sample Analysis / Method Comparison

Use for comparing a new method to a current method. (Optional)

Date:_____ **FREND™ System Analyte (test):** _____

Referral Lab:_____ **Comparison device**: _____

Note: Always attempt to check your FREND™ System against an identical system. If this is not possible, then you must determine bias before performing split sample analysis.

Bias, in this setting, is the consistent difference in results between two instruments measuring the same sample. Bias is caused by variations in instruments, testing methodology, and reagents. The amount of bias between any two instruments should remain relatively constant. (If a split-sample analysis is performed between two identical instruments and reagent systems, no bias factor is required, as the results would be expected to remain the same.)

DATE	TEST ID	FREND™ RESULT	CURRENT METHOD RESULT

Appendix (E): Reagent Log

- Record date of receipt and the lot number.
- If received new lot, external control should be ran.
- The condition of cartridges from the new shipment should be checked by testing external control.

Assay	Date of receipt	Lot Number	Exp. Date	Date QC passed	Shipment condition	Testing Analyst

Appendix (F): Temperature Log

Month_____ **Year**_____ **Location**_____

Day	Room Temp. 18 ~ 25 °C	Relative Humidity 20 ~ 80 %	Refrigerator 2 ~ 8 °C	Freezer < -20 °C	Comments/ Actions	Tech
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						

Appendix (G): Quality Control (QC) Log

Test item			FREND™ Serial Number	F10U -
Ex.QC Level 1 Lot #			Ex. QC Expiration Date	
Ex.QC Level 2 Lot #				

Range	Level 1	Low	Mean	High		Level 2	Low	Mean	High

Test Date (MM/DD)	Cartridge LOT#	QC Cartridge (Pass / Fail)	Level 1	Level 2	Tech/ Date
/		Pass / Fail			
/		Pass / Fail			
/		Pass / Fail			
/		Pass / Fail			
/		Pass / Fail			
/		Pass / Fail			
/		Pass / Fail			
/		Pass / Fail			
/		Pass / Fail			
/		Pass / Fail			
/		Pass / Fail			
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/		Pass / Fail			
/		Pass / Fail			
/		Pass / Fail			
/		Pass / Fail			
/		Pass / Fail			
/		Pass / Fail			
/		Pass / Fail			
/		Pass / Fail			
/		Pass / Fail			

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 five times, 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					
	New QC lot	/ /	1					
		/ /	2					
		/ /	3					
		/ /	4					
		/ /	5					
Test item & Cartridge lot #								
	Current QC lot	/ /	1					
		/ /	2					
		/ /	3					
		/ /	4					
		/ /	5					
	New QC lot	/ /	1					
		/ /	2					
		/ /	3					
		/ /	4					
		/ /	5					

Appendix (I): Specimen Log

Date	Patient ID	Patient Name	Dr.	PSA Result	TSH Result	Free T4 Result	Testo. Result	Vit.D Result	Tech

Appendix (J): Internal Procedural Control Error Code Log

Every FREND™ Cartridge contains an Internal (built-in) Procedural Control feature. Each time a test is run in FREND™ System, the procedural zone is scanned and it validates the functional integrity of reagents. Detailed function of procedural control is explained in CLIA Compliance Manual. When FREND™ Cartridge's procedural control is failed to show its validity, FREND™ System does NOT report the test result, instead, shows error code "EMTF-02, -04".

Failure of internal procedural control might be caused from:

- improper sample volume,
- incompletion sample capillary flow,
- incompatibility caused from unknown interferences,
- damaged cartridge, and
- Mishandling of cartridges.

Technical support in NanoEntek provides full support on identifying the cause of an error when it frequently appears during patient sample test. You may record EMTF-02,-04 errors to monitor the frequency of QC failure during the test. Please follow a guide "How to Back-up & Send Error Data" to send an e-mail with error data for further investigation. To find out more regarding other error codes, refer to Maintenance section on the FREND™ System Manual.

Address	240 Bear Hill Road, STE 101. Waltham, MA 02451
E-mail	**support@nanoentek.com**
Tel.	781-472-2558 Toll Free: 888-988-0108

To check FREND™ System version, go to Setup → System View

FREND™ Serial Number	**F10U**		
Software Version		**Firmware Version**	

Test Date	**Cartridge LOT#**	**Patient ID**	**Error Code**	**Repeat[1] (Y / N)**	**QC Cartridge[2] (Pass / Fail)**	**External QC run Level 1[3] (In / Out)**	**External QC run Level 2[3] (In / Out)**

[1] Re-test the same sample one more on another cartridge to check if the same error occurs. (Yes = Same Error code occurred)
[2] Run QC Cartridge to check system integrity. Write "Pass" if QC is passed.
[3] Run Level 1 and 2 of external QC solution from CLINIQA. If the results are within the range, write "in"
Check the record of QC if it passed or failed. If all results from external QC test are within the range, it is 'Pass'

Please attach this Log with the error back-up data from FREND™ System when sending an e-mail.

Appendix (K): How to Back-up & Send Error Data

This is a guide to backup FREND™ System data to USB flash drive. Section A explains how to back up the data from FREND™ System and Section B will guide you how to compress folders for the attachment on your e-mail to technical support team.

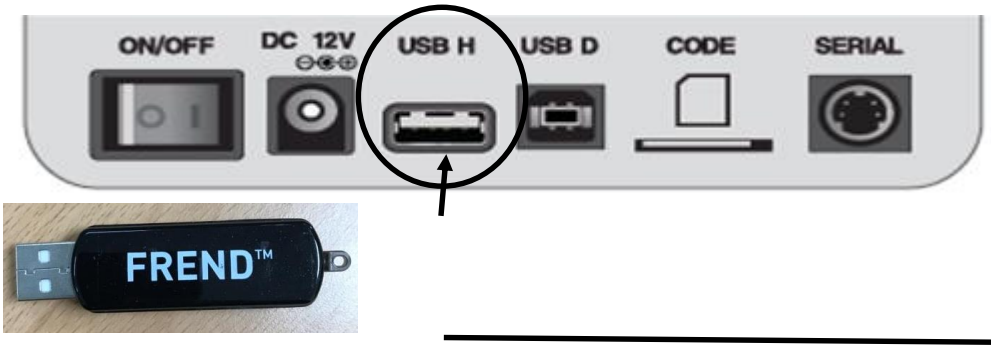
You will need,

1. USB Flash drive for FREND™
2. Desktop or laptop which has a USB port
   A. Windows / Mac OS (This example is prepared from Windows 10)
   B. Support all OS versions
3. FREND™ System

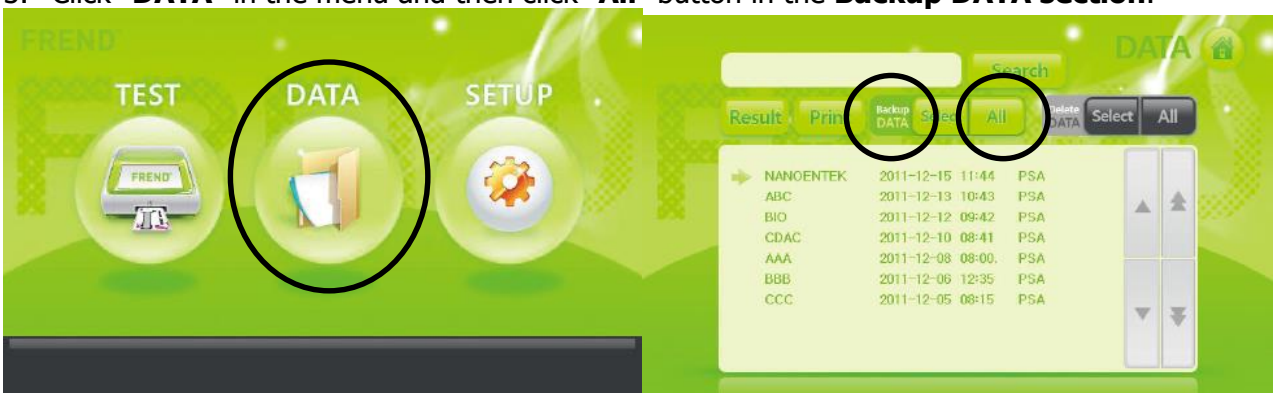
Section A. Back-up Data from FREND™ System

1. Before start, back-up all your data in FREND™ USB flash drive into your computer to secure all the data.
   **NOTE*: FREND™ System ONLY saves the latest sets of data.

2. Turn the FREND™ System on. Connect USB flash drive to the USB H on the back of the FREND™.



3. Click "**DATA**" in the menu and then click "**All**" button in the **Backup DATA section**.



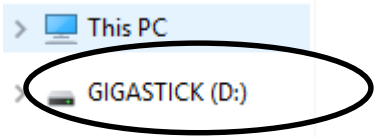
**NOTE*: Do NOT click All in Delete DATA section. It will erase all data.

4. After data back-up is completed, press OK to exit and disconnect USB flash drive.

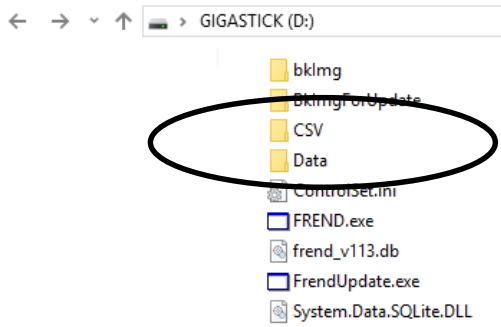
Appendix (K): How to Back-up & Send Error Data-continued

Section B. Send Backup Data to Technical Support

1. Connect USB flash drive to the computer. Find the "GIGASTICK (D:)" connected on your computer.

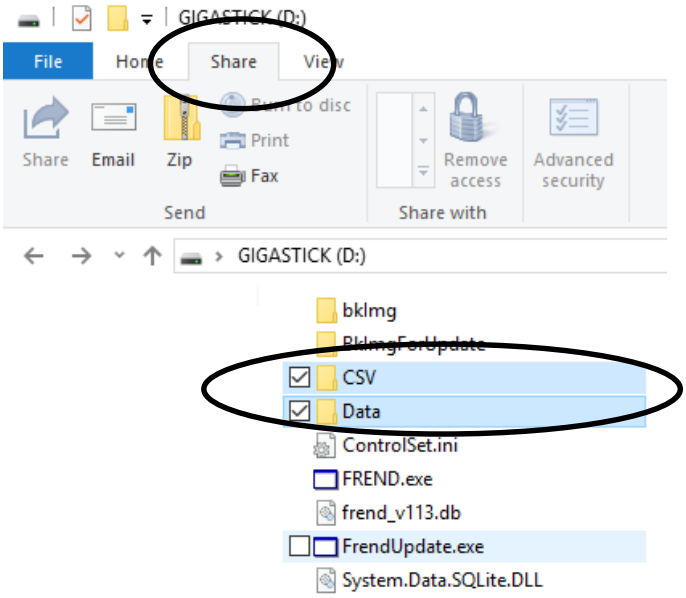


2. Open "**GIGASTICK (D:)**" and find two folders "**CSV**" and "**Data**"



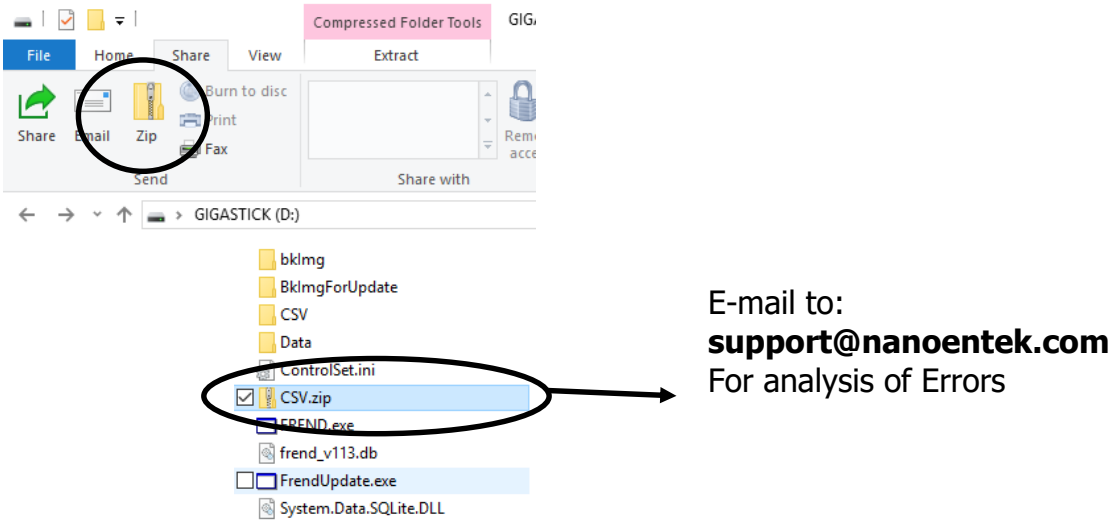
* List of files and folders shown in this list may vary depending on your USB flash drive, but you can find CSV and Data folders easily if the backup was successful from Section A.

3. Select two folders and click "**Share**" tap on top of the window.



Appendix (K): How to Back-up & Send Error Data-continued

4. Find "**Zip**" button to compress two folders into one. New "###**.zip**" file will appear.



5. Attach this "###**.zip**" file to **support@nanoentek.com** with the Error Code Log records.

**NOTE*: The name of .zip file can vary depending on your computer.

Appendix (L): Incident Management Investigation Report Form

Attach copies of all original reports, amended reports, instrument printouts, and any other documentation as necessary.

Person Reporting Incident:	Reporting Date	Incident Date:

Information of Person Affected by Incident					
Affected Person:			DOB:		Patient Staff Othe r
Ordering Physician:			Patient ID:		
Current Status:	Okay	Receiving Treatment	Hospitalized	Deceased	Unknown

Notified	**Name**	**Date Notified**
Physician		
Regulating		
Agency Ordering Physician		
Other Person		

Incident Description		
Error in phlebotomy or specimen collection procedure Misidentification of specimen Misidentification of patient Injury due to treatment	Misdiagnosis or injury based on test result Medication error based on test result Death based on test result Death Related to Treatment	Physical attack or abduction Failure in safety procedure Failure of instrument or methodology
Incident Description:		

True Cause Investigation Findings	
Factors	**Underlying Factors**
Human	HR Issues
Equipment	Information Management
Controllable Environment	Failure of Emergency responses
Uncontrollable environment	Leadership Issues
Other Factors_____	Other Factors_____
True Cause Investigation Findings:	

Appendix (L): Incident Management Investigation Report Form -continued

Patient Outcome
Patient Outcome:

Action Plan	
Opportunity for improvement	
Action to reduce reoccurrence	
Person Responsible for Implementation and Communication to Staff	
Implementation and communication Date	
Expected Results	

Action Plan Review	
Reviewer:	Review Date
Review Findings:	

Follow Up Actions			
	No action required Tag Incident for Monitoring Future Evaluation of Corrective Action	Staff training and in-service Staff competency assessment New policy or procedure Revision of policy or procedure	Cease Patient Testing Refer Patient Testing Resume Patient Testing

Reported By: _____ Reviewed By: _____

Follow Up Review By_____ Date Closed: __

Appendix (M): Laboratory Quality Incident & Correction Action

Attach copies of all original reports, amended reports, instrument printouts, and any other documentation as necessary.

Test System Affected:		Incident Date:
Analyte/Control Product:		Report Date:
Pre-Analytical	**Analytical**	**Post-Analytical**
◯	◯	◯
Incident Description:		
Corrective Action Taken:		
Special Actions Taken:		
Physician Notified Lab Dir. / TC Notified	Specimen Rejected Specimen Recollected	Test Result Amended Test Canceled
Was there a procedural change as a result of this occurrence?		
Assessment and Action taken to Prevent Recurrence:		
Lab Director or Designee:		
Tag Incident for Monitoring	Future Evaluation of Corrective Action	Update SOP

Reported By:_____ Date: _____

Reviewed By:_____ Date: _____

Date Closed: _____

Appendix (N): Corrective Action Log

Serial# F10U_____ Year

Date	Problem Encountered	Corrective Action Taken	Tech

Reviewed by:_____ Date: _____

Appendix (O): Maintenance Log

Daily	**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**
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: