



# Validation of System (Basic Test each Day)





#### 1.) Clean Prism

Clean prism three times with distilled water, dry lint free towel or Kimwipe between rinses



#### 2.) Zero



2b.) Zero Zero with USP water before Validation. \*\*Note the RI of USP water is 1.332987. ⊢ \*\*Clean the prism if the zero is abnormally offset ca. +/- 0.000010, as there may have been residual salts on the prism



#### 3.) Daily Calibration Validation





Load Water onto clean prism.







Validation Pass and Performance (Choose Performance. Choose Historical Graph)

| Validation                |                    |          |           | Honday                 | ?       |
|---------------------------|--------------------|----------|-----------|------------------------|---------|
| You are in Menu > Calibra | ation > Validation |          |           |                        |         |
| Live Reading :            | 1.332989           |          | Curre     | ent Temp : 2           | 20.00°C |
|                           | Expected           | Measured | Variation | Allowable<br>Variation | Result  |
| Water                     | 1.332987           | 1.332989 | 0.000002  | ±0.000100              | Pass    |
|                           |                    |          |           |                        |         |
|                           |                    |          |           |                        |         |
|                           |                    | 😧 Close  | e         |                        |         |
|                           |                    |          |           |                        |         |

| Performance                   |                  |                 |                |                | ? |
|-------------------------------|------------------|-----------------|----------------|----------------|---|
| You are in Menu > Calibration | on > Performance |                 |                |                |   |
| Measurements                  | Date             | Validation Grap | h for Water    |                |   |
| Today                         | Last 7 Days      | Last 30 Days    | Last 90 Days   | Custom         |   |
|                               |                  |                 |                |                |   |
| 1.333160 -                    |                  |                 |                |                |   |
| 1.333100                      |                  |                 |                |                |   |
| 1.333050 -                    |                  |                 |                |                |   |
| 1.333000                      |                  | <b>.</b>        | •              | •              |   |
| 1.332950 -                    |                  |                 |                |                |   |
| 1.332900                      |                  |                 |                |                |   |
| 1.332860                      |                  |                 |                |                |   |
| 1.332800                      | 64/2022          | £19/022         | F/11/2023      | 6/16/2022      |   |
| 12:08:54<br>PM                | 10:31:58<br>AM   | 12:24:57<br>PM  | 10:58:12<br>AM | 12:10:46<br>PM |   |
|                               |                  |                 |                |                | E |
|                               |                  |                 | a pro          |                |   |
|                               |                  |                 | V Print        | Close          | 2 |

If validation fails, clean the prism with water and alcohol wipes.



#### 1.) Add test sample

Place sample on prism

#### 2.) Highlight Measurement Method Push Start.



Highlight Measurement Press Start

| RUDOLPH<br>RESEARCH<br>ANALYTIC |                    | Disk Prot |                                |         | 6/26/2023<br>11:57:50  |
|---------------------------------|--------------------|-----------|--------------------------------|---------|------------------------|
| ♀ Smart Mea<br>Us               | sure™<br>er Fields |           |                                |         | Stop                   |
| Measurem<br>Sample Qual         | Operator<br>Dave   |           |                                | 6       |                        |
|                                 | CRN<br>123         |           |                                |         | Zero                   |
| Live Readir<br>Set Temp         | Patient ID<br>456  |           |                                | <b></b> | Menu<br>Data           |
|                                 |                    | Cancel    | 💙 Set                          |         | lidation               |
| Measuren                        | ient               | Reference | Hefract Index 20<br>Smart Disp | O Pe    | erformance<br>Readings |

Type in Tester's name, ID, Patient ID, or any other identifiers.

# Sample Pass Screen

| Drug ID       | : Water   |   |       |
|---------------|---|---|-------|
| Concentration | : 100 %   |   | =     |
| Manufacturer  | : Hospira USP Sterile Water                                   |   |       |
| Operator      | : Dave  |   | -     |
| UIN:2         |   | Base Material :   | Water |
| Negative R    | I variation : 0.000100   Variation : 0.000100   Result : PASS | Difference between<br>Measurement and Reference : 0.000 | 001   |
|               | [   | <b>0</b> or   |       |

List of sample types appears. Choose the sample type and concentration.



Type in Drug ID, Concentration, and Manufacturer of tested sample.



Push Set. Wait for results screen to appear. (Measurement delay dependent on sample being tested—10 to 60 seconds)

# Sample Fail Screen





#### 1.) Clean Prism

Clean prism three times with distilled water, wipe thoroughly with Alcohol wipe. Allow to dry.

# 2.) Zero

Zero the instrument on water as per page 1.

#### 3.) Add Reference Sample

- A.) Place pure sample on prism from. Fill entire prism area with sample.
- B.) Select Reference method. Push Start.
- C.) Follow screen instructions, and reload sample 3 times.
- D.) All three measurements must be nearly identical in RI value.





After first measurement, this box appears. Clean and reload the sample.

#### 4.) Add information for new reference drug.

Type in Drug ID, Concentration, Manufacturer and other custom field. Add the base solution of the drug (water or saline).





#### 5.) To Determine Alarm conditions

| Drug ID           | CONC      | Manufacturer                   | RI of Drug | water    | water dif | saline   | saline dif | Alarm (-) RI<br>10 % water dilution<br>** do not set alarm<br>below 0.000008 | Alarm (+) RI<br>10 % saline dilution<br>**do not set alarm<br>below 0.000008 | t1 | t2 | Final<br>Delay set<br>(s) | Background<br>Solution |
|-------------------|-----------|--------------------------------|------------|----------|-----------|----------|------------|--|--|----|----|---------------------------|------------------------|
| Duramorph         | 1 mg/mL   | West Ward Cedars Sinai         | 1.334572   | 1.332987 | -0.001585 | 1.334578 | 0.000006   | 0.000159   | 0.000001   | 10 | 40 | 40                        | saline                 |
| Ephedrine         | 5 mg/mL   | QuVa Pharma                    | 1.335267   | 1.332987 | -0.002280 | 1.334578 | -0.000689  | 0.000228   | 0.000069   | 10 | 10 | 10                        | saline                 |
| Fentanyl          | 50 mcg/mL | Hospria, West Ward, Akorn, Par | 1.333007   | 1.332987 | -0.000020 | 1.334578 | 0.001571   | 0.000002   | 0.000157   | 40 | 10 | 40                        | water                  |
| fentanyl dilution | 10 mcg/ml | hospirs/mmc Good Samaritan     | 1.33427    | 1.332987 | -0.001283 | 1.334578 | 0.000308   | 0.000128   | 0.000031   | 10 | 10 | 10                        | saline                 |

A.) Record the Average RI, and input into the VeriLinkRx Narcotics and Alarm conditions calculator (Excel)

B.) Drag down water and salt values, drag rows for calculations. Use these values as the positive and negative alarm conditions for your new sample

C.) Record the base material solution of drug.

D.) \*\*Note. Do not set an alarm condition less than 0.000008



### 6.) Populate custom fields

Populate custom fields, and save these values into VeriLlnkRx software. These can be later updated and/or corrected later in Library Manager.

| Edit Reference Measurement      |                                |  |  |  |  |  |
|---------------------------------|--------------------------------|--|--|--|--|--|
| Drug ID                         | User-Defined Ref 4             |  |  |  |  |  |
| Fentanyl                        |                                |  |  |  |  |  |
| Concentration                   | User-Defined Ref 5             |  |  |  |  |  |
| 50 mcg/mL                       |                                |  |  |  |  |  |
| Manufacturer                    | User-Defined Ref 6             |  |  |  |  |  |
| nospira                         |                                |  |  |  |  |  |
| Delay in secs.                  | Base Material                  |  |  |  |  |  |
| 60 📷 🛛                          | Undefined -                    |  |  |  |  |  |
| (Negative RI Variation) RI of R | eference Positive RI Variation |  |  |  |  |  |
| 0.000008 📻 1.33                 | 3007 0.000150                  |  |  |  |  |  |
|                                 |                                |  |  |  |  |  |
| Save                            | Save 😧 Cancel                  |  |  |  |  |  |