**Idylla™ Instrument Procedure**

1. **PRINCIPLE:**
   1. The Idylla™ System is an in vitro diagnostic (IVD) medical device, consisting of the Idylla™ Console and the Idylla™ Instrument. The System is intended for the detection of nucleic acid targets in various types of human samples, using disposable Test-specific Idylla™ Cartridges. Idylla™ processes sample to result, including liquefaction, cell lysis, DNA/RNA extraction, real-time amplification/detection, and data analysis and reporting.
   2. The System is intended for use with approved diagnostic Tests and other Assays using the Biocartis platform.
   3. The Idylla™ System consists of a Console, Instrument Module, Cartridge, and Assay Specific Software (Test-Type Package ,TTP):
      1. Console
         1. Touchscreen interface where users create a Test Request, monitor Test Progress, view, and export Test Results.
         2. The Console allows users to configure the system (e.g., add/delete user accounts, system configurations, etc.) and perform basic service and maintenance tasks (e.g., software updates, self-diagnostics test, etc.).
         3. An integrated barcode reader for scanning the Cartridge is also located on the Console.
      2. Cartridge
         1. Single-use container that holds the necessary reagents to perform specific assays. Small syringes within the Cartridge add buffers, mix reactions, and move the sample through microfluidic channels.
         2. Each Cartridge is individually packaged in a sealed pouch and discarded as waste after one use.
         3. The test-specific software package (TTP, or Test Type Package) must be installed on the Console to run a test Cartridge.
      3. Instrument
         1. Processes the test-specific Cartridge according to the corresponding TTP.
         2. The TTP directs the actions of the Instrument during test processing.
         3. The Instrument processes the sample and performs the assay. Instrument status is communicated to the user with a ring of white and red LED lights around the tray.



1. **PROCEDURE FOR OPERATION:**
   1. Turning on the System: The Console must remain on with the exception of mandatory power checks and/or maintenance.
      1. To switch on the Console, press the power On switch on the top right side of the console.
         1. **NOTE:** After a few minutes of inactivity, the Console monitor goes into power save mode with reduced backlight. To reactivate the screen from power-save mode, touch the screen.
      2. To turn on the instrument, press the power switch located at the back of the instrument in the I position.
         1. System initialization takes roughly one minute.
      3. After startup is complete, the white light below the tray indicates that the instrument is powered on and idle.
   2. Logging On/Off the System:
      1. On the **Status Overview** screen, tap **Log on**.
      2. Enter the appropriate username and password.
      3. Click **OK**.
      4. The Status Overview screen will appear, showing the action buttons in the menu bar and the name of the logged-on user at the top left of the menu bar.
         1. **NOTE:** Senior Technologist or designee can create/change/delete a username and/or password.
   3. Create a Test Request:
      1. To create a Test Request, click **New Test**.
      2. Scan the Soft Mol specimen label using the integrated console barcode reader.
      3. The Soft Molecular Order number will display in the **Sample ID** field.
         1. **NOTE**: Quality control testing:
            1. The control ID can be entered manually by clicking the **Sample ID** field then typing the desired control ID.
            2. Click the **Mark as QC Test** checkbox to designate QC testing.
      4. Scan the barcode on the top of the test cartridge.
         1. The test details will be displayed in the cartridge information fields.
         2. The system will automatically supply the Test Type and Sample Type information.
      5. If necessary, enter additional information in the **Comment** field.
      6. Verify all entry fields contain accurate information.
      7. Click **Confirm** to finalize the test request. Once the test request is finalized, the system automatically starts the test when the cartridge is inserted.
   4. Cancelling a Test Request: A test can be cancelled only if the run has not been started.
      1. Click **Test List** on the console menu bar.
      2. In the list, select the Test Request that you want to delete.
      3. Tap **Cancel Test**.
      4. Click **OK** to confirm the test cancellation.
   5. Aborting a Test in Progress: A test can be aborted while it is in process. A reason for stopping the run must be provided. A cartridge cannot be reused once a run is aborted.
      1. Click **Test List** on the console menu bar.
      2. In the list, select the Test with status in progress that you want to abort.
      3. Tap **Abort Test** to cancel the request.
      4. Enter a reason for aborting the Test in the comments field.
      5. Tap **Confirm**. The Instrument will stop processing the test and reset.
   6. View the Test Result: Idylla™ Explore software is used to generate result reports for samples and controls run on the instrument. However, the test result is also available on the console.
      1. On the **Status** **Overview** screen, click the **Results** icon next to the completed Test.
      2. To view the Test result using the Test List screen, tap **Test** **List**, then appropriate test.
         1. The Test Result screen shows basic test information, including final result.
      3. Generate a Result Report:
         1. Click **PDF** **Report** on the report screen.
         2. If applicable, click **Export** **PDF** to store the PDF on an external storage device.
      4. View Assay Log: The Assay Log contains raw data from each test and can be used for troubleshooting.
         1. Insert an encrypted flash drive into a USB port located on the back of the console.
         2. Click **Export Assay Logs** on the report screen.
         3. Tap **Export** and save the log to the encrypted flash drive.
   7. Turning off the system: The Console must remain on with the exception of mandatory power checks and/or maintenance.
      1. Verify all tests and/or software updates are complete.
      2. Log off the console.
      3. Press the power on switch on the top right side of the console.
      4. Then, push the power switch, located at the back of the instrument, in the 0 position.
2. **MAINTENANCE:**
   1. Record completed maintenance on the appropriate Idylla Instrument Maintenance log found in the Idylla instrument binder.
   2. All errors and instrument issues must be recorded on the Idylla Instrument Error log.
   3. **Daily:**
      1. Clean work area:
         1. Follow daily cleaning practices according to the Molecular Genomic Laboratory Quality Management Program.
      2. Discard used cartridges:
         1. Used cartridges must be removed from the instrument and discarded in biohazard trash.
   4. **Monthly:**
      1. Environmental Control:
         1. Place 50 uL of deionized water in a 1.5 mL tube.
         2. Wet a swab with deionized water and wipe all prep surfaces, keyboard, and instrument console/module.
         3. Place the swab in the previously prepared 1.5 mL tube.
         4. Aliquot 30 uL of the deionized water into the sample well of the assay cartridge.
         5. Run the cartridge on the instrument following assay QC procedure.
         6. Print a result report from the Idylla and place in the appropriate instrument binder.
            1. On the **Status** **Overview** screen, click the **Results** icon next to the completed Test.
            2. To view the Test result using the **Test** **List** screen, tap **Test** **List**, and then the Test for which you want to view the result from the list.
            3. Click **PDF** **Report** on the report screen.
            4. Click **Export** **PDF** to store the PDF on an external storage device.
            5. Save the exported PDF on the MGPGenomicsData$ drive in the Idylla folder and print a copy for the instrument binder.
         7. Result control in Soft Molecular per standard procedure.
         8. If the environmental sample is positive:
            1. Clean all areas that were tested.
            2. Repeat testing using one sample for each surface area:

Countertop

Keyboard

Instrument Console

Instrument Module

* + 1. Cleaning the Idylla™ Instrument:
       1. **NOTE**: Do **not** clean the instrument while processing samples and/or adding samples to Cartridges. Do **not** spray cleaning solution directly on the Instrument or Console. Be careful with liquids near electrical parts.
       2. Use the following materials to clean and disinfect the parts of the System:
          1. Kim Wipes
          2. 70 % Isopropanol or ethanol
          3. Water.
       3. Cleaning of the Console, instrument and bar code reader.
          1. Turn off the instrument and console.
          2. Wet Kim Wipe with 70% Isopropanol or ethanol.
          3. Wipe all surfaces and let air dry.
          4. Wet a Kim Wipe with water.
          5. Wipe all surfaces.
          6. Dry the surfaces with a dry Kim Wipe.
          7. Power the instrument back on.
       4. Cleaning the Cartridge Tray:
          1. In the unlikely event of a spill inside the Cartridge tray, you must first open the tray, then power off the Instrument before cleaning and decontaminating the Cartridge tray.
          2. Contact Biocartis Customer Support when spills occur inside the Cartridge tray.
          3. **NOTE**: Do not try to close Cartridge Tray manually. The Tray will close automatically when powering the Instrument back on.
    2. Perform Instrument Self-Diagnostic Test:
       1. Verify all cartridges have been removed from the instrument.
       2. On the Status Overview screen, select the name of the Instrument for which you want to perform a self-diagnostic Test.
       3. Click **Diagnostic** **Test**.
          1. **NOTE:** The Test takes approximately 30 minutes, during which time, the Instrument is not available.
       4. Once the self-diagnostic test is complete:
          1. If the test is successful, the instrument can be used for testing.
          2. If the test fails, the Instrument is no longer available for running Tests.

On the Status Overview screen, status is displayed as **out of order**.

Contact Biocartis Customer Support for assistance.

* + - 1. A self-diagnostic Test report can be saved for later use.
      2. Use a USB storage device to save and export report.
  1. **Yearly**:
     1. The Idylla™ instrument yearly maintenance which is performed by Biocartis technical support.
     2. A warning will appear on the console 30 days before the maintenance due date.
        1. **NOTE**: When yearly maintenance is overdue, it will be noted on the reports generated by the instrument.
        2. **NOTE**: Only tests labeled RUO can be run on the instrument when the maintenance period has expired. Only a Senior Technologist or designee can allow diagnostic testing when the maintenance is overdue.
        3. To allow diagnostic test to be run on the overdue System:
           1. Click **Menu**.
           2. In the System Setting section, click **More**.
           3. Click the **Maintenance Due Settings** section to be able to edit the settings.
           4. Select **Allow cartridges to run when instrument maintenance is overdue**.
           5. Click **Save**.
  2. **As Needed:**
     1. Calibrate the Console Touch Screen:
        1. Click **Menu**.
        2. In the Maintenance section, click **Calibrate Touch Screen**.
        3. Click the touch screen following the instructions displayed on the screen. Be careful to accurately press the instructed points.
     2. Install Software Updates:
        1. **NOTE:** This is performed by Senior Technologist or designee.
        2. Verify all tests running on the instrument are complete.
        3. Required software packages or updates must be obtained from Biocartis.
           1. Software packages can be downloaded from <https://secure.biocartis.com/#/login>
           2. Enter the appropriate username and password.
           3. Save the software package on an encrypted flash drive.
        4. Click **Menu**.
        5. In the Update Software section, click:
           1. **Console**: Security certificates, a console software update, or a console software patch.
           2. **Instrument**: Instrument software updates
           3. **Test Type**: Test Type package
        6. Select the desired installation schedule.
        7. Select the required software packages on the encrypted flash drive.
        8. Highlight the packages to be installed, then click **Install**.

**NOTE:** When installing software updates, the console may automatically restart before and after the installation. The instrument may experience downtime of up to 15 minutes per software update.

1. **TROUBLESHOOTING:**
   1. Refer to Table 2 for a list of system errors and troubleshooting steps.

**Table 2:** Idylla Instrument Troubleshooting

Table

Description automatically generated with medium confidence

1. **CONTACT INFORMATION:**
   1. Biocartis US, Inc
      1. Email: [customerserviceUS@biocartis.com](mailto:customerserviceUS@biocartis.com)
      2. Phone: 1-844-443-9552
2. **REFERENCES:**
   1. Idylla™ Operator Manual (CSW/4.3).
   2. Idylla™ System Site Preparation Guide.
   3. Idylla™ Safety Sheet.
   4. Test-specific Instructions for Use (IFU) per Idylla™ Test.