# Addendum #01 for RFP #0919335097

Project Name: State Hygienic Laboratory – Lab D129 Modifications

DAS RFP #: 0919335097

DAS Project #: 9096.00

Date: 2/18/2019

Addendum #1:

- Cover Page – Table of Contents
- Exhibit A: Pre-proposal meeting minutes and sign-in sheet (4 pages)
- Exhibit B: GSP Equipment Product Data. (16 pages)

Questions Due: **February 21st, 2019**

Proposals Due: **March 1st, 2019**

**END OF ADDENDUM #1**

**February 15, 2019 at 9:00 AM**

**Owner/DAS/CM Team Introductions:**
Iowa Department of Administrative Services (DAS) – Jennifer Kleene
State Hygienics Laboratory
Construction Manager – DCI Group – Michael Steen
DAS Purchasing Agent – Steve Oberbroeckling

**General Project Description/Overview:**

1. Design and construction administration for the removal of casework and plumbing modifications needed for installation of new equipment.
    a. New equipment will be provided and installed by owner. Equipment is PerkinElmer Genetic Screening Processor. Product data will be included in addendum.
    b. Dust control will be of high importance during construction and design documents shall address temporary partitions.

**Bid Package Process:**
Overview of Instructions to Bidders – DCI Group

PROPOSALS DUE: **March 1st, 2019** at 2:00 PM

MAKE SURE IT IS SUBMITTED TO DAS AS THE REQUEST FOR PROPOSALS READS

2. Proposal Process
    a. Ensure all sections of 4.2 Proposal Content are included in proposal.
    b. Proposal shall include a Not-to-Exceed estimate for reimbursable expenses.
    c. Review Section 5.2 and ensure each of the criteria for evaluation are met.
    d. All questions after this meeting and prior to February 21st, to be submitted to Steve Oberbroeckling at steve.oberbroeckling@iowa.gov. Do not contact DAS or DCI Group directly for questions or clarifications.

3. Schedule
    a. Questions due **February 21st, 2019** by 4:00 PM CST
    b. An addendum will be issued to incorporate minutes and sign-in sheet from this Pre-Proposal Meeting.
    c. Final addendum will be issued no later than **February 26th, 2019** by 2:00 PM CST or no later than 48 hours prior to proposals being due.
    d. Proposals due **March 1st, 2019** by 2:00 PM CST
    e. Tentatively an NOI will be issued by March 8th, 2019
    f. Tentatively the execution of contract is to be completed by March 22nd, 2019
    g. It is anticipated the development of construction documents to be completed by April 26th, 2019 and contract bidding to take place April 29th, 2019 – May 15th, 2019.
    h. Anticipated construction work to begin May 2018

**Scope of Work Overview:**

1. Administrative
    a. Agreement between the Owner and Designer will be a modified ConsensusDocs 803
    b. Designer shall use the State of Iowa's Project Management Software, EADOC, throughout the duration of the project.
    c. Successful Designer shall provide construction administration, including but not limited to, development of submittal master list (pre-con and close-out), submittal reviews, review and responses to RFIs, development of Architectural Supplemental Instructions for design revisions, change order review, review of Trade Contractor pay applications, periodic site visits, attendance at project meetings as required, and participation / development of contractor punch list.
    d. Designer shall be responsible for issuing meeting agendas and minutes for all meetings during the design phases.
    e. All staff working on the project will need to have background checks completed before working at the State Hygienics Laboratory.

2. Evaluation, Design, & Construction
    a. Provide all disciplines necessary for complete design of the project.
    b. The Labs will remain occupied throughout construction. Construction shall be phased to accommodate staff and operations at the Labs.
    c. Designer shall satisfy all Federal and State codes. The Design Professional will coordinate and be the main contact to life safety, energy, and all other applicable codes include submission for plan review to the State Fire Marshall's office. All applicable fees with the departments will be covered by the Design Professional.
    d. Designer shall provide cost opinions at 100% DDs and 100% CDs.
    e. Final submission of contract documents to include drawings and specifications for bidding. Designer to develop a complete set of specifications except for Division 00 and Division 01 which will be provided by DCI Group to incorporation into the designer specification book. The designers' specifications shall include all Technical Specifications. DCI Group will distribute the Division 00 documents for incorporation into the Designer's specifications.
    f. Field Observation reports shall be submitted to DCI Group for each site inspection within five (5) days of the site visit.
    g. As part of design and construction, the designer shall, at a minimum, attend ten (10) site visits as follows: one (1) kick-off meeting, one (1) 100% design development document review meeting, one (1) 95% construction document review meeting, one (1) pre-bid meeting, one (1) construction kick-off meeting, two (2) construction reviews, one (1) substantial completion/punch list development, one (1) punch list approval, and one (1) one-year warranty correction period visit. This total does not include visits for review and

documentation of existing conditions which shall be as-needed to accomplish design work.

3. Close out
    a. Provide Construction As-Builts drawings and specifications of all design modifications, including ASIs, PRs, COs and RFIs in both CAD and PDF formats.
    b. Review and approval of close-out documentation.
    c. Development and verification of punch list document with assistance from Construction Manager.
    d. Provide inspection and date for substantial completion along with Construction Manager.

**State Rules**

1. No smoking or smokeless tobacco use onsite.

**Open Discussion**

1. 100% CD Budget will need to be uploaded to EADOC prior to releasing documents to bid per State code.
2. If bids are 20% higher than the cost opinion, the designer will be required to redesign the project to bring it within budget.
3. Designer shall request SFMO exemption review.
4. Questions:
    a. Question: Will the contractor need to install the equipment that will be provided by the owner?
    Answer: No, the owner-provided equipment will be installed by the manufacturer after the room modifications have been completed.

    b. Question: What is the construction budget?
    Answer: Approximately $16,000

    c. Question: Are CAD drawings available?
    Answer: Yes, there is a CAD drawings available showing the room layout, but it does not include power, HVAC or plumbing details.

5. Site Review
    a. New equipment shall be on emergency power circuit
    b. (4) new GSPs will be installed
    c. Existing casework and sink will not be reinstalled
    d. Design shall confirm that current HVAC system will handle the added load
    e. Data outlets will need to be provided for new equipment
    f. Equipment will hook up to deionized water and existing drain
        i. Equipment does not need to drain into hazardous waste drain but drain piping from equipment to drain shall be rated to handle deionized water.

DCI GROUP
DESIGN + CONSTRUCTION INTEGRATION

**Project Name:** 9096.00 SHL Lab D129 GSP Modifications

**Meeting Purpose:** Pre-Proposal Meeting

**Date:** February 15th, 2019 at 9:00 AM

## Attendees

| Initials | Name | Company | Phone Number | E-Mail Address |
|---|---|---|---|---|
| M | Michael Steen | DCI Group | 515-975-8348 | michaels@dcigroup-us.com |
| GA | Garrett Arganbright | DCI Group | 641-757-9791 | garretta@dcigroup-us.com |
| K | Jennifer Kleene | DAS | 515-745-0454 | jennifer.kleene@iowa.gov |
| | Bill Messinger | DAS | 515-204-5983 | bill.messinger@iowa.gov |
| DC | Dan Gates | DAS | 515-208-2014 | dan.gates@iowa.gov |
| | Josh Davenport | DAS | 515-393-1697 | joshua.davenport@iowa.gov |
| DLS | Don Simmons | State Hygienics Lab | 515-725-1600 | donald-simmons@uiowa.edu |
| TJH | Travis Henry | State Hygienics Lab | 515-725-1600 | travis-henry@uiowa.edu |
| | Kari Boyens | IMEG | 515-371-5327 | kari.l.boyens@imegcorp.com |
| | Eric Henderson | IMEG | 630.717.2433 | eric.y.henderson@imegcorp.com |
| | Dennis Bennett | Twin Rivers Engineering | 515-288-3679 | dbennett@twinriverseng.com |
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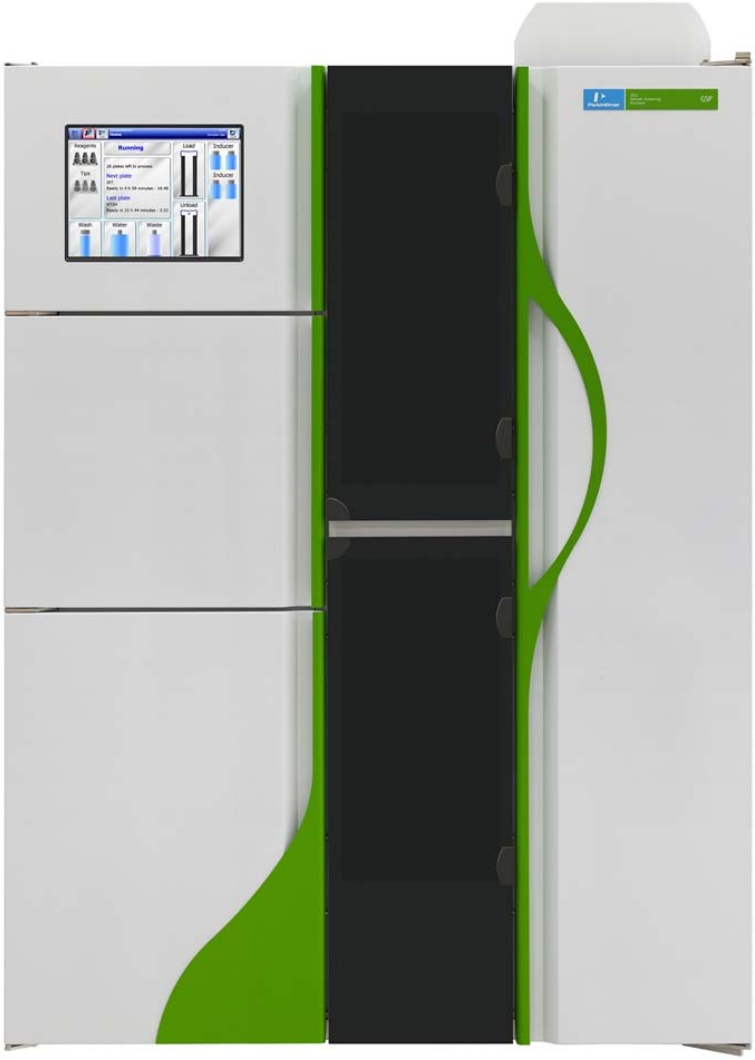
# 2021-0010 GSP®

## Genetic Screening Processor

## IQ & OQ September 2016

### Instrument Qualification & Operational Qualification



PerkinElmer®
For the Better

Name: 70016774 Revision: D

# 01. IQ – Installation Qualification (Pre-Installation)

GSP, Genetic Screening Processor Installation Qualification

| | |
|---|---|
| **Instrument Serial Number** | 2021- |
| **Customer company name** | |
| **Address** | |
| **Address line 2** | |
| **Date of site survey** | |
| **IQ finish date** | |

## Document history

| Number | Release |
|---|---|
| 70016774 | First version |
| 70016774 | A – Minor corrections |
| 70016774 | B – Changes only to OQ |
| 70016774 | C – Changed information regarding 2nd network card in WorkStation PC. |
| 70016774 | D – Changes only to OQ |

# Introduction

## Objective

The objective of this document is to detail the environmental and facilities requirements necessary for proper installation and operation of the 2021-0010 GSP Genetic screening processor. The completed process demonstrates that the equipment meets the vendor-developed standards of operation and safety, and performs the functions specified by the manufacturer.

## Scope and Responsibility

PerkinElmer is responsible for providing trained personnel, the IQ/OQ elements outlined in this plan and verifying that these elements are fully executed and documented.
The customer is responsible for accepting the terms of this plan and providing the facility with all environmental requirements for the proper installation of the 2021-0010 GSP Genetic screening processor.
The customer is responsible for providing personnel and assistance to PerkinElmer for implementing the IQ/OQ outlined in this document.

## Need to Re-Qualify

The instrument needs to be re-qualified if the facilities where the instrument has been located are changed and OQ related tests are repeated after major service.

## Copyright Information



## Trademarks

# Protocol Documentation

## Signatures

The signature of a PerkinElmer trained personnel as well as the signature of the customer is required on the last page of the IQ report with the acceptance date.

## Calibration/Expiration dates

MM/YY format will be used to denote dates. Reagents are valid until the last day of the month noted.

## Temperature

All temperatures will be given in the unit of Celsius (°C)

## Blank Areas

All text-fields have to be filled – there can be no blank fields.

## Acceptance Criteria

All requirements and specifications tests have to be accepted and approved by the customer.

## Archive

The original document should be left with the customer. A copy should be attached to the installation report and submitted to the manufacturer according to internal protocol.

# IQ – Installation Qualification (Pre-Installation)

The service engineer/application specialist must do a site survey (including the instrument transport route in the building to the lab) before installation, to ensure that the instrument requirements for space, weight, electricity, and laboratory environment are fulfilled. Preferably the instrument should be placed in the laboratory so that the service engineer has easy access to the sides and back of the instrument. However, as the GSP instrument has wheels that can be used short term (for long term the instrument feet should always be used), placement against a wall is also possible but some space between the instrument and the wall is recommended to improve air-flow.

## 1. Site requirements

### Instrument dimensions

| | Width | Depth | Height | Weight |
|---|---|---|---|---|
| **GSP Instrument Crate** | 1510 mm | 990 mm | 2030 mm | 740 kg |
| **GSP Instrument** | 1310 mm | 760 mm | 1950 mm | 620 kg |

In addition to the instrument itself, an external PC (WorkStation) is supplied with the instrument. This can be placed anywhere in the laboratory if the GSP will be network connected. If the instrument is not connected to the network, the WorkStation PC has to be linked to the instrument with a cross-over network cable (supplied with the instrument).

☐ The above specified dimensions and requirements do not present a problem

## 2. Electrical specifications

A dedicated circuit is recommended for the GSP instrument. In addition, it is recommended that a UPS is installed (order separately) to secure continuous power to the instrument.

| | Yes | No |
|---|---|---|
| The instrument will be connected to a UPS system | ☐ | ☐ |

### Instrument Power consumption

| | VA Maximum | Supply Voltage | Hz |
|---|---|---|---|
| **2021 GSP** | 1500 | 100 - 240 | 50/60 |

☐ The above specified electrical specifications do not present a problem

## 3. Laboratory environment requirements

The operating temperature of the GSP instrument is 18 – 30 °C. The inside of the instrument is regulated to 25 °C. Please record the temperature and humidity at the time of the visit.

| | | | At the time of site survey |
|---|---|---|---|
| **Temperature range** | 18 – 27 °C | 28 - 30°C | |
| **Relative humidity if the above temperature** | 10 - 80 % | 10 - 65 %. | |

Normal clean laboratory environment is required.

☐ The laboratories environmental requirements are met

## 4. Heat emission

The heat emission mainly depends on the temperature of the laboratory.

- Typically 2200 BTU/h (laboratory temperature 22°C)
- Maximum 3400 BTU/h (laboratory temperature 30°C)

☐ The above specified heat emission does not present a problem in the laboratory

## 5. Water requirements

The recommendation for GSP is deionized water which should fulfil the requirements stated in the *"Clinical and Laboratory Standards Institute. Preparation and Testing of Reagent Water in the Clinical Laboratory: Approved Guideline-Fourth Edition. CLSI Document C03-A4, (ISBN 1-56238-610-7), 2006 ".* The temperature of the deionized water should be 15°C - 30°C.

| | **Clinical Laboratory Reagent Water (CLRW)*** |
|---|---|
| **Highest amount of bacteria allowed (CFU/mL)** | 10 |
| **Resistivity / Conductivity** | ≥ 10 MΩ/cm (25°C) / ≤ 0.1 µS/cm |
| **Silicate (SiO2, mg/L)** | ≤ 0.05 |
| **Particles** | ≤ 0.22 µm |
| **TOC** | 500 ppb (ng/g) |

* Clinical and Laboratory Standards Institute. Preparation and Testing of Reagent Water in the Clinical Laboratory: Approved Guideline-Fourth Edition. CLSI Document C03-A4, (ISBN 1-56238-610-7), 2006

It is recommended that the GSP instrument is connected directly to an external water source and waste drain. Preparations for the water line connections need to be started well before installation. If connected to a water line, the full capacity of the instrument can be used, and this also reduces the manual work needed in the lab when using the GSP.

There are certain requirements on the deionized water source/line when connected to the GSP:

- The pressure in the water line should be 0.5-5 bar (7.25-72,5 psi). Several instruments can be connected to the same water source, as long as the minimum pressure is kept at all times. It is possible to go under 0.5 bar pressure momentarily without causing instruments to fail because the instrument always keeps a buffer level of 3L in the internal water bottle, and will try getting water again after a short while.

- If there is no or weak pressure from the water system, then semiautomatic mode can be used on the GSP which will engage a peristaltic pump for pumping the water. Pumping is recommended to be done from an open water source, as under dimensioned waterline can cause problems for the peristaltic pump.

- Deionized water minimum flow is 1 L/min (both for automatic and semiautomatic mode). If the flow is less than that, the instrument will stop filling up water after 30 seconds, but try again after a short while.

- The water source needs to supply 12 litres/hour/instrument connected (worst case scenario, in normal use 5-6 litres/hour/instrument is needed). The instrument uses approximately 1 litre/plate processed that has a washing step (TSH, IRT, T4, 17OHP & BTD).

- The flow rate of the peristaltic pump Pu6 (semiautomatic/manual mode) is approximately 2.2 L/min

- The connector where the GSP's external water tube connects to a water mains line should be of size 3/8" (picture below) and suitable for a 16mm/10mm reinforced PVC tube. Brass fittings should not be used on DI water lines. The connection is prepared by the customer so that the service engineer can connect the tube during instrument installation. A clamp should be used to secure the tube to the connector. Use the one supplied with the instrument or a clamp similar to the one in the picture below. If the connection is not ready at the time of installation, the external water bottle can be used as the instruments clean water source until the connection has been prepared.

| | |
|---|---|
| **The customer verifies that if a pressurized water line is used, the pressure does not exceed 5 bar** | |
| **The type of water filtering system used:** | |

☐ The water requirements are met

## 6. Waste requirements

The GSP kits contain calibrators and controls manufactured from human blood components. The human blood has been tested using FDA approved methods or equivalent and found to be negative for hepatitis B surface antigen, anti-hepatitis C and anti-HIV 1 and 2 antibodies. Nevertheless, all recommended precautions for the handling of blood derivatives should be observed. Please refer to the U.S. Department of Health and Human Services publication "Biosafety in Microbiological and Biomedical Laboratories" or any other local or national regulation.

Reagents contain sodium azide (NaN3) as a preservative. Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. On disposal, it is recommended to flush with a large volume of water to prevent azide build-up.

A 0.5% Na-hypochlorite solution is used for disinfection of the instrument once/month. Na-hypochlorite is a corrosive liquid. Obtain and read the "Material and Safety Data Sheet" (MSDS) from the supplier before use. Special care should be taken when handling this solution.

Disposal of all waste should be in accordance with local regulations.

Flow rate of the peristaltic waste pump Pu1 is approximately 2.2 L/min.

☐ The above specified waste specifications and requirements do not present a problem.

# 7. IT requirements

## Instrument Internal PC (Master Node)

- No additional software should be installed to the instruments internal PC. This includes Anti-virus software, firewalls & remote access software.
- The Windows user accounts and their rights need to be left as they are.
- The instrument PC should not be connected to a domain.
- If any of the above prevents the instrument from being allowed to be directly connected to the network it should be linked to the WorkStation using a crossover network cable.
- All Instrument PC's and WorkStation PC's connected to the same network need unique IP-addresses.

## WorkStation PC

- Anti-virus and other software can be installed to this PC if needed.
- The Windows user accounts cannot be removed and their rights need to be left untouched.
- If the instrument will be connected to the WorkStation directly through a crossover network cable it should be connected to the 2nd network card in the WorkStation PC, marked "GSP".

## Remote diagnostics (LogMeIn)

In order to be able to perform remote diagnostics of the instrument at least the WorkStation PC needs to be connected to the Internet. LogMeIn is PerkinElmer's official remote support tool. Clearance from customer IT should be obtained before using this program. Depending on the firewall setup some modification might be needed to allow LogMeIn to remotely access PC's. Remote diagnostics could allow for shorter down-time and faster troubleshooting if there is a problem.

☐ The above specified IT specifications and requirements do not present a problem.

# 8. Additional consumables needed for installation or training

- Na-Hypochlorite solution (reagent grade) is needed for disinfection of the instrument. This can be ordered from any manufacturer at any strength (usually 5-15% solution), a final solution of 0.5% is used for the disinfection. PKI does not supply this solution.

# 9. GSP WorkStation setup information

Before installation the person who will be setting up the GSP WorkStation should have the information outlined in the GSP Configuration Manuals "Preparing for configuration" section so that it can be setup to work with the customers systems and to the customer needs after the GSP instrument installation is finished. If the person setting up the WorkStation is not the same person who will be doing the instrument installation these should coordinate to get all the needed information.

☐ The needed information for the WorkStation configuration has been collected.

# Signatures

By signing this document the signatory confirms that the requirements and specifications have been reviewed and accepted.

### PerkinElmer trained personnel

| Name | Signature | Date |
|---|---|---|
| | | |

### Customer

| Name | Signature | Date |
|---|---|---|
| | | |

# 02. Installation & OQ – Installation checklist & Operational Qualification

GSP, Genetic Screening Processor Installation checklist and Operational Qualification

| | |
|---|---|
| **Instrument Serial Number** | 2021- |
| **Customer company name** | |
| **Address** | |
| **Address line 2** | |
| **OQ finish date** | |

## Document history

| **Number** | **Release** |
|---|---|
| 70016774 | First release |
| 70016774 | A – Minor corrections |
| 70016774 | B – Updated to include new features included in GSP instrument software version 1.4.<br>• Automatic washer test setup included<br>• Tip tightness reduction to 1 test instead of 3<br>• Tip tightness test limits changed<br>• “Save Configuration” step added after LV tip tightness test. |
| 70016774 | C – Instructions for Reagent Storage Cooler improved to clarify the need for the loop in the tube.<br>Additional checkbox added for Test kit test run |
| 70016774 | D – Removed step 41 "Check that Power Options are correct" since it is no longer needed. Changed layout of tip tightness test result fields. Changed order of some checkboxes. |

# Introduction

## Objective

The objective of this document is to detail the steps and tests needed to ensure proper functionality of the 2021-0010 GSP Genetic screening processor. The completed process demonstrates that the equipment meets the vendor-developed standards of operation and performs the functions specified by the manufacturer.

## Scope and Responsibility

PerkinElmer is responsible for providing trained personnel, the IQ/OQ elements outlined in this plan and verifying that these elements are fully executed and documented.
The customer is responsible for accepting the terms of this plan and providing the facility with all environmental requirements for the proper installation of the 2021-0010 GSP Genetic screening processor.
The customer is responsible for providing personnel and assistance to PerkinElmer for implementing the IQ/OQ outlined in this document.

## Need to Re-Qualify

The instrument need to be re-qualified if the facilities where the instrument has been located are changed and OQ related tests are repeated after major service.

## Copyright Information



## Trademarks

# Protocol Documentation

## Signatures

The signature of a PerkinElmer trained personnel as well as the signature of the customer is required on the last page of the OQ report with the acceptance date.

## Calibration/Expiration dates

MM/YY format will be used to denote dates. Reagents are valid until the last day of the month noted.

## Temperature

All temperatures will be given in the unit of Celsius (°C)

## Blank Areas

All text-fields have to be filled – there can be no blank fields.

## Acceptance Criteria

All steps need to be performed, all tests have to pass and the document needs to be approved by the customer.

## Archive

The original document should be left to the customer. A copy should be attached to the installation report and submitted to the manufacturer according to internal protocol.

# Installation procedure

Before the installation can begin, the IQ-part of the IQOQ needs to be complete.

A typical installation takes around 2-3 days if all preparations have been done beforehand and if there are no problems.

Items to make sure you have on-site before starting the installation:

- ☐ 3060-0010 GSP Test Kit (1 per instrument)
- ☐ 61007161 GSP Service Kit (1 per customer site or engineer)
- ☐ 4080-0010 GSP Wash Concentrate – 1 bottle per instrument with 1 extra bottle per site.
- ☐ 3304-0010 GSP Inducer – 1 box (containing 3 bottles) per instrument.
- ☐ DI water source or DI bottled water
- ☐ Pallet jack (for moving the crate and removing the instrument from the crate)

## Checklist

☐ 1. Check shipping containers and shock sensors for damage. Create a complaint if there is any damage.
- ☐ None of the shock sensors were activated
- ☐ One or more of the shock sensors were activated and a complaint was opened.

☐ 1. Remove the instrument from the shipping crate

☐ 2. Unwrap the instrument

☐ 3. Remove all transportation locks
- ☐ 3a. Touch Screen door locking screw
- ☐ 3b. LV & HV Pipette zip-ties
- ☐ 3c. Manipulator long belt zip-ties
- ☐ 3d. Manipulator grabber zip-tie & manipulator table locking screw and bushing
- ☐ 3e. Washer module manifold & plate mover zip-ties
- ☐ 3f. Bulk Dispenser zip-tie
- ☐ 3g. Disk Remover zip-tie
- ☐ 3h. Measurement Module optic blocks & plate mover zip-ties
- ☐ 3i. Liquid module wash solution bottle, mixing bottle & wash concentrate bottle zip-ties

☐ 4. Install the Thermal Control Unit

☐ 5. Install the Reagent Storage Cooler with tube and loop

☐ 6. Connect PC battery fuse

☐ 7. Install the internal Water and Waste bottles

☐ 8. Install the USB keyboard/touchpad

☐ 9. Connect external Water and Waste (Select 1 water and 1 waste option)
- ☐ Instrument DI water source is a pressurized water DI water source
- ☐ Instrument DI water source is a water source that is not pressurized
- ☐ Instrument DI water source is an external water bottle
- ☐ Instrument waste is connected to an external bottle
- ☐ Instrument waste is connected to a drain

☐ 10. Connect instrument power cable

☐ 11. Boot instrument to service mode and record the version of the instrument software (Update to the newest available version if not installed)

| | |
|---|---|
| GSP Instrument Software version: | |

☐ 12. Start Reagent Storage temp control

Steps 13-28 can be performed while the reagent carousel is still cooling down.

☐ 13. Do a “Reset” for the Reagent module

☐ 14. Load tip & reagent cassettes to the reagent carousel

1 Full LV tip cassette with LV label
1 Empty LV cassette with LV label
1 LV cassette with 5+ tips and no label
1 Full HV tip cassette with HV label
1 Empty HV cassette with Waste label
1 HV cassette with 5+ tips and no label
1 Reagent cassette with 2 small reagent vials and anti-evaporation caps

☐ 15. Set Water and Waste settings

☐ 16. Set how many Inducer bottles will be used

☐ 2 Inducer bottles used
☐ 4 Inducer bottles used

☐ 17. Set up the automatic Washer test

☐ 18. Set Instrument UI language

☐ 19. Set PM date to today

☐ 20. Save and check configuration

☐ 21. Check scale readings and adjust if needed

☐ Scales were adjusted (Configuration saved and checked)
☐ There was no need to adjust the scales

☐ 22. Get a few litres of water to the internal water bottle

☐ 23. Prime LV pipette with 10 000 µl

☐ 24. Reset & Prime Bulk Dispenser with 50 ml of water and 10 ml of inducer

☐ 25. Run a 15 minute shuffle test for LV tips, HV tips and anti-evaporation caps.

| | Result | Minimum | Maximum |
|---|---|---|---|
| Tip and cap shuffle moves: | | 100 | - |
| HVD - Tip quality detection signal | | 0 | 100 |
| LVD - Tip quality detection signal | | 0 | 100 |

☐ All 3 shuffle tests passed on first try
☐ There was a problem with one or more of the tests and a complaint is opened

☐ 26. Install the plate magazines to the Input and Output Stackers

☐ 27. Attach Stacker doors

☐ 28. Reset the Manipulator and run a 15 minute shuffle test

| | Result | Minimum |
|---|---|---|
| Shuffle moves completed | | 100 |

☐ The Manipulator shuffle test passed on first try

☐ There was a problem with one or more of the tests and a complaint is opened

☐ 29. Attach Air vents

☐ 30. Run and pass 1HV and 1 LV tip tightness tests

| | Pressure | Pressure drop | Pressure limit | Pressure drop limit |
|---|---|---|---|---|
| **HV Tip Tightness test** | | | **20,0 – 40,0** mbar | **<1,0** mbar |
| **LV Tip Tightness test** | | | **19,0 – 33,0** mbar | **<0,5** mbar |

☐ Both Tip tightness tests passed on first try

☐ There was a problem with the HV tip tightness test and a complaint is opened

☐ There was a problem with the LV tip tightness test and a complaint is opened

☐ 31. Save configuration

☐ 32. Remove all cassettes from the reagent storage and throw away the used tips

☐ 33. Print Test Report (save report page to file).

☐ 34. Place the instrument at its final location, attach the feet and level the instrument

☐ 35. Unpack and setup WorkStation PC

☐ 36. Check and set WorkStation PC time-zone and time

☐ 37. Connect instrument to WorkStation OR connect both to lab network

☐ The instrument is connected to the WS PC with a cross-over network cable

☐ The instrument and the WS PC are both connected to the same network

☐ 38. Configure and test the connection between instrument and WorkStation

☐ 39. Save configuration

☐ 40. Adjust time-zone and time on Instrument PC

☐ 41. Do a final check that all tubes are properly fitted to avoid floods

☐ 42. Pour a bottle of wash concentrate to the wash concentrate bottle

☐ 43. Reboot instrument to Normal mode and pass startup

☐ The instrument passed startup on the first try

☐ The instrument did not pass startup on the first try and a complaint is opened (unless the startup failed because of human error)

- ☐ 44. Pump some water to the instrument
- ☐ 45. Load Inducer bottles (room temperature)
- ☐ 46. Load full LV-tip, full HV-tip, empty waste-tip and Test-kit test cassettes
- ☐ 47. Run and pass Washer test
  - ☐ The washer test passed on the first try
  - ☐ The washer test passed on the second try after the manifold was washed
  - ☐ More than 2 washer tests had to be run before passing and a complaint was opened.
- ☐ 48. Run and pass the Test-kit tests
  - ☐ All 3 Test kit tests passed on the first try
  - ☐ Adjusting the Reagent module was required before the test passed
  - ☐ More action was required to get the tests to pass and a complaint is opened.
- ☐ 49. Start the Service program (with the manager still running) and Print report when all the tests have passed
- ☐ 50. Take a copy of the “C:\GSP” folder and the saved test reports
- ☐ 51. Make an Instrument backup folder on the WorkStation PC
- ☐ 52. Fill out and send in the installation form with attached test reports and log folder
- ☐ 53. Create a complaint if there were any actions aside from what is described in the instructions that had to be done in order to get the instrument working (DOA instrument).
- ☐ 54. Customer satisfaction ensured.

## Signatures

By signing this document the signatory confirms that the steps in this document have been performed and that the results have been reviewed and accepted.

### PerkinElmer trained service engineer

| Name | Signature | Date |
|---|---|---|
| | | |

### Customer

| Name | Signature | Date |
|---|---|---|
| | | |