

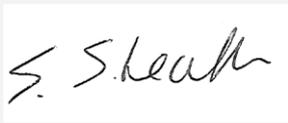
PINPOINT Study Laboratory Research SOP

**IT IS THE RESPONSIBILITY OF ALL USERS OF THIS SOP TO ENSURE THAT
THE CORRECT VERSION IS BEING USED**

All staff should regularly check the R&D Unit's website and/or Q-Pulse for information relating to the implementation of new or revised versions. Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.

The definitive versions of all R&D Unit SOPs appear online. If you are reading this in printed form check that the version number and date below is the most recent one as shown on the R&D Unit website: www.research.yorkhospitals.nhs.uk/sops-and-guidance/ and/or Q-Pulse

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Approved by:	Name/Position:	Lydia Harris, Head of R&D
	Signature:	
	Date:	13 th July 2022
	Name/Position:	Sarah Sheath, SOP Controller
	Signature:	
	Date:	13 th July 2022

This SOP will normally be reviewed at least every 3 years unless changes to the legislation require otherwise

Version History Log

This area should detail the version history for this document. It should detail the key elements of the changes to the versions.

Version	Date Implemented	Details of significant changes
1.0	18 th July 2022	

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1 Introduction, Background and Purpose

Full Study Title:	PINPOINT:
Local Project Reference:	311006SY
Principal Investigator:	Dr James Turvill
Recruitment Target:	1,000 per year
Sponsor:	Cancer Health Alliance

Primary Objective: To determine the accuracy and viability of using the results of pre-determined laboratory blood tests that are entered into an algorithm to generate a percentage likelihood that a participant currently under investigation for cancer will receive a positive diagnosis.

Depending on their investigational pathway, either new or residual blood samples will be collected from participants and a series of pre-defined tests will be performed by the Trust's local laboratories. The result of these tests will be anonymised, then reported to the R&D team for use in the PINPOINT algorithm.

2 Who Should Use This SOP

Research and Development (R&D) Laboratory staff who have a valid Good Clinical Practice (GCP) training certificate, an up-to-date Research CV and have signed onto the Study Delegation and Signature Log.

3 When this SOP Should be Used

This SOP should be used when performing trial related activities. The frequency of each research activity is outlined in the table below:

Tasks	Frequency
Data entry into <i>PINPOINT_Data</i> workbook	Perform this task daily .
Retrieve and add additional tests to residual serum samples	Perform this task daily .
Request residual serum samples to be sent from Scarborough General Hospital	Perform this task as required . <i>Note: requests for rapid diagnostic patient residual serum samples should be made before 09:30 where possible.</i>
Enter test results into <i>PINPOINT_Data</i> workbook	Perform this task twice weekly . <i>Note: perform this task on a Monday and</i>

Thursday, before the RAP pathway data gather.

Request residual serum samples to be sent from Scarborough General Hospital

Perform this task **as required**.

Note: requests for rapid diagnostic patient residual serum samples should be made before 09:30 where possible.

4 Procedure(s)

4.1 Data Entry

4.1.1 Generating a New 'PINPOINT master workbook'

On the first working day of each month, a new '*PINPOINT_master_workbook*' should be generated to enable maximum fluidity in the delivery of the trial and should be completed prior to running the '*RAP*' data gather. To do this:

1. Navigate to the '*10. PINPOINT Data Master Spreadsheet*' folder, open the '*Template*' subfolder and then the '*PINPOINT_master_workbook_template*' file.
2. Click on '*File*', then '*Save As*' from the dropdown menu.
3. Navigate back to the '*10. PINPOINT Data Master Spreadsheet*' folder.
4. Name the file as '*PINPOINT_master_workbook_currentmonth2022*'.

e.g. *PINPOINT_master_workbook_may2022*

4.1.2 Gathering Rapid Diagnostic Pathway Patient Data

1. Log into Blood Sciences Combined Telepath.
2. Type '*LIST*' and enter.
3. Type '*RAP*' and enter. '*RAP*' is the code required to gather test result data from patients that have had a rapid diagnostic test screen requested via ICE.
4. Type '*G*' and enter.
5. Now you will then be prompted to enter the date range. Use the format DD.MM.YY or if today's date; type '*T*' and enter. Gather the results from the previous working day. If the data gather is done after a weekend and/or bank holiday the date range gather must include the weekend and/or bank holiday.
6. Press the '*Esc*' key when prompted to do so. It may take a period of time to gather the data depending on the number of tests in the given time period. When it has finished it will display the message '*Gather finished OK*' under '*Status message from gathering routine.*'

7. Type '*P*' and enter.
8. Type '*1*' and enter.
9. Type '*L*' and enter.
10. Type '*HFS*' and enter.
11. Name the file as '*RAPIDYYMMDD*' i.e. '*RAPID*' followed by the date in reverse.
12. Type '*W*' and enter.
13. Type '*Y*' and enter. The plain text file has now been exported to the '*chem*' folder in the HFS drive.

4.1.3 Converting Plain Text Files to Excel Workbooks

1. Open the HFS drive.
2. Open the '*chem*' folder.
3. Cut the '*RAPID*' plain text files and paste into the '*08. Data Gathers*' folder. Do not copy the plain text file.

```
X:\Biochemistry\01. Trials Info\Studies OPEN (RESEARCH SPECIALITY)\ONCOLOGY\PINPOINT\08. Data gathers
```

4. Open Microsoft Excel.
5. Click on '*File*', then '*Open*' from the dropdown menu.
6. Select '*All Files*' from the dropdown menu.
7. Navigate to the '*08. Data Gathers*' folder and select the required plain text file.
8. Click '*O**pen*'.
9. Click '*D**elimited*'.
10. Click '*N**ext >*'.
11. Unselect '*T**ab*' and select '*S**emicolon*'.
12. Click '*F**inish*'.
13. Hold '*Ctrl*' and highlight rows 1-5 and 7-8, right click on the mouse and select '*D**elete*'.
14. Select cell 1A, hold '*Ctrl*' and '*T*'. Ensure '*M**y table has headers*' is selected then click '*Q**K*'.
15. Sort the table so that it displays the participant data grouped by location. To do this- select the drop-down menu on '*Specimen no.*' and then select '*S**ort A-Z*'.

1	Date Rec'd	Specimen no.	PAT	Name	DOB/Age	Location	GP	RDC
	09	Example-01	01.01.51	Stillington S N H Metce	R			
	09	Example-02	01.01.51	Pocklington S Antill	R			
	09	Example-03	01.01.51	My Health S Unknown	R			
	09	Example-04	01.01.51	Stillington S Unknown	R			
	10	Example-05	01.01.51	For EDI TESI For EDITE	R			
	09	Example-06	01.01.51	Posterngate JA Batty	R			
	09	Example-07	01.01.51	Whitby Gro M Dunwel	R			
	09	Example-08	01.01.51	Terrington S Unknown	R			
	09	Example-09	01.01.51	Whitby Gro R C Chand	R			
	09	Example-10	01.01.51	Millfield Su HE Iredale	R			
	09	Example-11	01.01.51	Scarboroug S Unknown	R			
	09	Example-12	01.01.51	Priory Medi Unknown	R			
	09	Example-13	01.01.51	Escrick Surg HP Senara	R			
	09	Example-14	01.01.51	Front Street Unknown	R			
	09	Example-15	01.01.51	Hackness R Unknown	R			
	09	Example-16	01.01.51	Whitby Gro Unknown	R			
	09	Example-17	01.01.51	Priory Medi C Darroch	R			
	09	Example-18	01.01.51	Haxby Grou Unknown	R			
	09	Example-19	01.01.51	Whitby Gro R C Chand	R			

- Specimen numbers beginning with 'W,YY' have been tested and are located in York.
- Specimen numbers beginning with 'Q,YY' have been tested and are located in Scarborough.

16. Hold '*Ctrl*' and highlight columns *F-H*, right click on the mouse and select '*Delete*'.

17. Click on '*File*', then '*Save As*' from the dropdown menu.

18. Navigate to the '*08. Data Gatherers*' folder.

19. From the '*Save as type:*' drop down menu select '*Excel Workbook*'.

20. Click '*Save*'.

4.2 Requesting Residual Samples from Scarborough

4.2.1 Generating an Aliquot List

This Task should be performed whenever samples belonging to participants from Scarborough General Hospital are identified via their specimen number in the daily '*RAP*' gather (See 4.1.3 for details).

1. Using the '*RAP*' workbook from the current day- Hide all rows containing residual sample data for York participants. To do this, highlight rows, right click on the mouse and select '*Hide*'.
2. Click on '*File*', then '*Save As*' from the dropdown menu.
3. Navigate to the '*09. Scarborough RAP Sample Request Lists*' folder.

```
X:\Biochemistry\01. Trials Info\Studies OPEN (RESEARCH
SPECIALITY)\ONCOLOGY\PINPOINT\09. Scarborough RAP Sample
Request Lists
```

4. Name the file as 'SGHYMMDD' i.e. 'SGH' followed by the date in reverse.
5. Send copy of finalised 'SGH' aliquot list to Susan.North@york.nhs.uk and Hannah.Longman@york.nhs.uk using subject '*PINPOINT residual aliquot request*', this will be used by the SGH team to send the requested samples via the daily laboratory transport. Once received, the details of their receipt must be recorded in '*Section 07. Specimen Receipt Log*' in the Laboratory Site File.

4.3 Requesting PINPOINT specific tests

4.3.1 Ensure Sample is Eligible for Additional Testing

Only samples that have been tested for a specific series of tests are eligible for additional PINPOINT testing. This is because only the PINPOINT specific test codes are non-reportable, so anything else that is added would go against the trials' ethical guidelines.

1. Log into Blood Sciences Combined Telepath.
2. Type 'SENQ' and enter.
3. Copy the participants' Specimen number from the 'RAP' workbook.
4. Return to Telepath and right click on the mouse next to '*Specimen number*' to paste the participants' specimen number into this field. Check the participants gender, then ensure the following tests were requested:
 - Full Blood Count (test code 'FBCY' or 'FBC')
 - U&E levels (test code 'UE2' or 'OUE4')
 - LFT levels (test code 'LFT')
 - Bone Profile (test code 'BONE2')
 - CRP level (test code 'CRP')
 - For female participants only-
 - CA-125 level (test code 'CA125R')
 - For male participants only-
 - PSA level (test code 'CA125R')
5. If any of the above tests were not requested, record on 'RAP' workbook next to appropriate row of data then click 'Save' icon.

4.3.2 Retrieving Residual Serum Samples via cITM

IMPORTANT: This task should be performed for York residual samples ONLY.

cITM is available on the desktop of all computers in the laboratory and can be accessed via the start menu or by entering the IP(or web) address 10.131.178.154

(<http://svycitm2/cobasit/cobasit.html>) in the web browser field.

1. Open cITM.
2. In the global information area, select the 'Log on' button.
3. Log into cITM using the generic archive log on:
 - Username: **YORKARC**
 - Password: **CITM123**
4. Ensure that the location selected in the global information area is 'YORK'.
Otherwise, select the drop-down menu and select 'York' as the location.
5. Refer back to the 'RAP' workbook. Hide all rows containing residual sample data for Scarborough participants. To do this, highlight rows, right click on the mouse and select 'Hide'.
6. Select the first cell on the list in column B that contains a specimen number. Hold 'Ctrl' and press 'C'.
7. Return to cITM and paste the specimen number into the search bar in the global information area. To do this, select the blank box then hold 'Ctrl' and press 'V'.
8. Delete the first 5 and last 2 characters of the specimen number, leaving only the 7-digit specimen number in the search box. Click the button containing a magnifying glass, which will be located to the right of the search box.

This search should return data for 1 sample, and be displayed as follows:

Samples: 1



STAT	Sample ID	Sample location	Collection date/time	Sample type	Patient	Patient ID	Priority	Order date/tir
<input type="checkbox"/>	5765731	(60070 (95))	19/05/2022 10:45:00	Serum			Routine	19/05/2022 17

9. Transcribe the sample location into the column titled 'cITM location' in the 'RAP' workbook.

Please note: If the sample has received a request for a coeliac screen test; the location will appear on cITM as the location '{YORK PIANO}'. When this occurs:

- a) Select the arrow button farthest right of the sample information.
- b) Select the drop down arrow next to 'More details'.
- c) Obtain the location of the primary sample from the 'Archive position:' field, then transcribe this into the 'cITM location' column on the 'RAP' workbook.

Sample: 5800250 Serum			
▼ More details			
Priority:	Routine	Collection date/time:	31/05/2022 10:00:00
Order location:	York - Scarborough		
Sample location:	{61645 (82)}	Location state:	
Archive position:	{61645 (82)}	Archiving date:	01/06/2022 15:23:44
Orderer phone No.:	01904 794141	Ordering doctor:	
Host order No.:	5800250	Orderer:	B82100
Tube type:		Primary/aliquot:	Primary tube
Sample volume:	412	Sample quality:	

10. Repeat for all eligible participants.
11. Once list is complete, select 'File', then 'Print' from the dropdown menu.
12. Use list to locate and retrieve samples from the fridges located in the Biochemistry laboratory.

Please note: the 5-digit number refers to the rack number, whilst the number in brackets refers to the specific position that contains the sample.

Example: {60070 (95)}

13. When retrieving samples, ensure that approximately 1mL residual serum remains. If it doesn't, return sample to its archived location, record on print out then on 'RAP' workbook next to appropriate row of data, ensuring you save the file following this.
14. Send copy of finalised 'RAP' workbook to pinpoint.study@york.nhs.uk using subject 'Eligible PINPOINT participants', this will be used by the team for consent approaching and trial costings.

4.3.3 Adding Additional Test Requests onto Residual Samples

1. Log into Blood Sciences Combined Telepath.
2. Type 'SENQ' and enter.
3. Copy the participants' Specimen number from the 'RAP' workbook.
4. Return to Telepath and right click on the mouse next to 'Specimen number' to paste the participants' specimen number into this field.
5. Type 'Q' and enter.
6. Tab up to field '6) Sets' and enter the appropriate test code- 'FPIN' or 'MPIN'- depending on the participants gender.
7. Press enter until all fields in the specimen enquiry screen become blank.
8. Repeat for all participants, then load all samples onto the pre-spun rack, located in drawer 4 of the (IPB) module of the Cobas 8100.

IPB Layout

URGENT SAMPLES	GENERIC SAMPLES	GENERIC SAMPLES	PRE-SPUN SAMPLES
GENERIC SAMPLES	GENERIC SAMPLES	GENERIC SAMPLES	SCM ERRORS (Short samples/ poor barcodes/ not booked into Telepath)
Drawer 1	Drawer 2	Drawer 3	Drawer 4 (Right)

4.4 Entering Rapid Diagnostic Pathway Patient Data

This process transcribes the data for all eligible participants from the 'RAP' workbook into a 'master_workbook', where participant information and test result data will be stored. To do this:

1. Copy the data from the 'RAP' workbook and append it to the active 'PINPOINT_master_workbook'. To do this:
 - a. Highlight the data in the 'RAP' workbook you wish to copy. Do not include any headings.
 - b. Hold the 'Ctrl' key, then press the 'C' key simultaneously.
 - c. Open the active 'PINPOINT_master_workbook' belonging to the month you are currently in.

```
X:\Biochemistry\01. Trials Info\Studies OPEN (RESEARCH SPECIALITY)\ONCOLOGY\PINPOINT\10. PINPOINT Data Master Spreadsheet
```

- d. Select the first empty cell in column A. Hold the 'Ctrl' key, then press the 'V' key simultaneously.

- e. Remove duplicates. Where there is a duplicate specimen number, the row will highlight red. Delete one of the rows highlighted red. The remaining row will go colourless when its duplicate is deleted.
- f. Click on '*File*', then '*Save*' from the dropdown menu.

4.5 Processing PINPOINT Test Results

This task should be completed once per week on a Monday, prior to completing daily '*RAP*' data gather and all other PINPOINT trial related tasks.

4.5.1 Gathering Rapid Diagnostic Pathway Patient Data

1. Log into Blood Sciences Combined Telepath.
2. Type '*LIST*' and enter.
3. Type '*PIN*' and enter. '*PIN*' is the code required to gather test result data from female participants that have had additional tests requested as part of the PINPOINT trial.
4. Type '*G*' and enter.
5. Now you will then be prompted to enter the date range. Use the format DD.MM.YY or if today's date; type '*T*' and enter. Gather the results from the previous 7 days, including weekends and bank holidays.
6. It will take a period of time to gather the data depending on the number of tests in the given time period. When it has finished it will display the message '*Gather finished OK*' under '*Status message from gathering routine.*'.
7. Type '*P*' and enter.
8. Type '*1*' and enter.
9. Type '*L*' and enter.
10. Type '*HFS*' and enter.
11. Name the file as '*PINYYMMDD*' i.e. '*PIN*' followed by the date in reverse.
12. Type '*W*' and enter.
13. Type '*Y*' and enter. The plain text file has now been exported to the '*chem*' folder in the HFS drive.
14. Repeat the above, substituting the code '*PIN*' with '*PIN2*' to gather and save test result data from female participants that have had additional test requested as part of the PINPOINT trial.

4.5.2 Converting Plain Text Files to Excel Workbooks

2. Open the HFS drive.
3. Open the '*chem*' folder.

4. Cut the '*PIN*' and '*PIN2*' plain text files and paste into the '*Test Results*' subfolder located in the '*08. Data Gatherers*' folder. Do not copy the plain text file.

```
X:\Biochemistry\01. Trials Info\Studies OPEN (RESEARCH SPECIALITY)\ONCOLOGY\PINPOINT\08. Data gathers\Test Results
```

5. Open Microsoft Excel.
6. Click on '*File*', then '*Open*' from the dropdown menu.
7. Select '*All Files*' from the dropdown menu.
8. Navigate to the '*Test Results*' subfolder located in the '*08. Data Gatherers*' folder and select the '*PIN*' plain text file.
9. Click '*O**pen*'.
10. Click '*D**elimited*'.
11. Click '*N**ext >*'.
12. Unselect '*T**ab*' and select '*S**emicolon*'.
13. Click '*F**inish*'.
14. Hold '*Ctrl*' and highlight rows 1-5 and 7-8, right click on the mouse and select '*D**elete*'.
15. Select cell 1A, hold '*Ctrl*' and '*T*'. Ensure '*M**y table has headers*' is selected then click '*O**K*'.
16. Click on '*File*', then '*Save As*' from the dropdown menu.
17. Navigate to the '*Test Results*' subfolder located in the '*08. Data Gatherers*' folder.
18. From the '*Save as type:*' drop down menu select '*Excel Workbook*'.
19. Click '*Save*'.
20. Repeat steps 6-19 for '*PIN2*' plain text file.

4.5.3 Entering PINPOINT Additional Test Data

1. Copy the data from the '*PIN*' and '*PIN2*' workbooks and append it to the active '*PINPOINT_master_workbook*'. To do this:
 - a. Use the active '*PINPOINT_master_workbook*' to cross-reference the participants awaiting results from the previous week with the test result data from the '*PIN*' and '*PIN2*' workbooks. Highlight the test result data for the specific participant in the '*PIN*' or '*PIN2*' workbook you wish to copy. Do not include any headings. Do not include rows without results. Ensure abnormal test result checks have been performed.

- b. Hold the 'Ctrl' key, then press the 'C' key simultaneously.
- c. Open the active '*PINPOINT_master_workbook*' belonging to the month you are currently in.

```
X:\Biochemistry\01. Trials Info\Studies OPEN (RESEARCH SPECIALITY)\ONCOLOGY\PINPOINT\10. PINPOINT Data Master Spreadsheet
```

- d. Select the empty cell in row G in the column of which participant you wish to transfer the test result data for, then hold the 'Ctrl' key, and press the 'V' key simultaneously.
- e. Repeat for all participants awaiting results from the previous week.

4.5.4 **Identifying and Actioning Abnormal Test Results**

1. Any tests that have been requested as part of the PINPOINT trial that return results outside the minimum value reference ranges for a participant of undefined age/gender will become highlighted when test result data is pasted into the active '*PINPOINT_master_workbook*'. Should such an instance occur:

- a. Open the '*Abnormal result crib sheet*' file located in the '06. Laboratory Manual & SOPs' folder.

```
X:\Biochemistry\01. Trials Info\Studies OPEN (RESEARCH SPECIALITY)\ONCOLOGY\PINPOINT\06. Laboratory Manual & SOPs
```

- b. Cross-reference the information provided in the crib sheet to determine whether the 'abnormal results' that were highlighted as precaution in the '*PINPOINT_master_workbook*' are true abnormal results.
- c. If this is the case, copy all data for the affected participant/s by holding 'Ctrl', highlighting both column 1 and the column in which their data is contained and press 'C' simultaneously.
- d. Select '*File*', '*New*' then '*Create*' to open a new workbook.
- e. Paste the abnormal data into the new workbook by holding the 'Ctrl' key and press the 'V' key simultaneously.
- f. Select '*File*' then '*Save as*' and save the file as '*ABNORMALRESULTSYYMMDD*' i.e. '*ABNORMALRESULTS*' followed by the date in reverse.
- g. This data must be sent **immediately** to a clinician for further investigation. To do this:

Send copy of the '*ABNORMALRESULTS*' file to James.Turvill@York.NHS.UK using subject '*Abnormal PINPOINT results*', and flagged as '*high importance*'.

4.6 Finalising the 'PINPOINT master workbook'

At the beginning of each month, a finalised list of Rapid Diagnostic Pathway patients whose residual blood samples were tested as part of the PINPOINT trial two months prior, who have now given their retrospective consent, will be sent to labs. Any data from those who did not consent must be deleted.

5 Related SOPs and Documents

Research and Development (Q-Pulse)

R&D/S19 Processing Laboratory Research Samples

R&D/F51 Specimen Receipt Log

6 Appendix A

Not applicable at this stage.