PinPoint Urol Test

Instructions For Use

pinpoint

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1. About This Document

1.1. About This Document

Read this Instructions For Use document carefully and completely before attempting to set up or use the PinPoint Urol Test.

This Instructions For Use document provides the information required to:

- Setup the PinPoint Urol Test prior to clinical use
- Use the PinPoint Urol Test in a clinical setting

This Instructions For Use document is maintained online.
For the latest version of this document, please refer to www.pinpointdatascience.com.

1.2. Symbols Glossary

Symbol	Meaning
	Manufacturer
	Catalogue number
	Consult instructions for use
	Caution
	In vitro diagnostic medical device
	"UKCA Mark" – this product fulfils the requirements of the UK Medical Devices Regulations 2002 (SI 2002 No. 618, as amended) (UK MDR 2002)

1.3. Definitions & Abbreviations

Term	Meaning
AUC	Area Under Curve
HL7	Health Level 7
IT	Information Technology
IVD	In vitro diagnostic medical device
LIMS	Laboratory Information Management System
NPV	Negative Predictive Value
PinPoint Risk Score	The result produced by the PinPoint Test. This is a number between 1 and 2000, and is only to be interpreted with reference to clinical guidance.
ROC	Receiver Operating Characteristic
UK	United Kingdom
UK MDR	UK Medical Devices Regulations
UKCA	UK Conformity Assessment

Unit of Measure	Meaning
µmol/L	Micromoles per Litre
µU/L	Microunits per Litre
fL	Femtolitres
g/L	Grams per Litre
IU/L	International Units per Litre
kU/L	Kilounits per Litre
L/L	Litres per Litre
mg/L	Milligrams per Litre
mmol/L	Millimoles per Litre
U/L	Units per Litre

Analyte	Meaning
AFP	Alpha-fetoprotein
ALT	Alanine Transaminase
CA125	Cancer Antigen 125
CA15-3	Cancer Antigen 153
CA19-9	Cancer Antigen 199
CEA	Carcinoembryonic Antigen
CRP	C-reactive Protein
HCG	Human Chorionic Gonadotropin
MCV	Mean Corpuscular Volume
PSA	Prostate-Specific Antigen
RBC	Red Blood Cell
RDW	Red Cell Distribution Width
WBC	White Blood Cell

2. Product Information

2.1. Product Overview

The PinPoint Urol Test is a software-based *in vitro* diagnostic device to be used in the triage of cancer diagnosis.

The PinPoint Urol Test takes a panel of 30 commonly analysed blood-based biomarkers plus other clinical data (age and sex) as inputs to proprietary machine learning algorithms, and aggregates signals into a single quantitative score – the PinPoint Risk Score – which indicates the risk that the patient has cancer. The PinPoint Risk Score is a number between 1 and 2000, and is to be interpreted with reference to clinical guidance.

The PinPoint Urol Test is one of the tests available in the PinPoint Test Suite provided by PinPoint Data Science, with each test targeted for different cancer sites.

2.2. Intended Purpose

The PinPoint Urol Test is intended for use as a decision support tool, to aid in triaging patients who have symptoms that may suggest urological cancer.

The PinPoint Urol Test uses blood-based biomarkers and other clinical data as inputs to machine learning algorithms, and returns a quantitative score indicating the risk that the patient has cancer.

Triage results should be treated as presumptive, and subsequent confirmatory testing should be performed. Results should be considered in the context of the patient's history and presence of clinical signs and symptoms consistent with Urol cancer.

The PinPoint Urol Test is to be used by healthcare professionals in a primary or secondary care environment.

2.3. Indications For Use

The PinPoint Urol Test is intended for professional use only by healthcare professionals in a primary or secondary care environment for testing of adults (age 18+) already suspected of having urological cancer.

2.4. Summary of Test Procedure

The PinPoint Urol Test operates following this high-level procedure:

1. A patient presents with symptoms that may suggest urological cancer
2. The clinician requests a PinPoint Urol Test through their existing test management system
3. A blood sample is obtained from the patient and is sent to the relevant pathology laboratory
4. The pathology laboratory analyses the patient's blood sample for the required test analytes using their existing laboratory equipment, and records the analyte measurements in their existing laboratory information management system
5. The analyte values are sent to the PinPoint Urol Test
6. The PinPoint Urol Test generates a PinPoint Risk Score

7. This PinPoint Risk Score is sent back to the pathology lab and returned to the clinician through their existing test management system

8. The clinician is then presented with the PinPoint Risk Score which is used to support a triage decision, in accordance with their organisational clinical guidance and their own clinical judgement.

2.5. Principle of Operation

The PinPoint Urol Test uses a combination of machine learning (gradient boosting) and statistical modelling (logistic regression) to produce a risk score that the tested patient has cancer, where a higher test result indicates a higher risk of cancer.

The underlying principle is that the machine learning algorithm has been trained on a data set which comprises a large number of examples of patients who had blood measurements and whose cancer status was known. This training allows the machine learning algorithm to learn a set of relationships between those blood measurements and the cancer status of the patient. These relationships can then be used, along with a blood test for a new patient, to predict how likely it is that the new patient has cancer.
The algorithm the device uses is trained and validated during production of the device. Once trained, the predictive algorithm is fixed, and the device does not automatically update its training using data it receives after it is deployed.

Another view of this approach is that it is a systematic method for combining a larger number of more modest signals (from the individual blood measurements) into a single, much stronger cancer signal.

The returned test result is a risk score, with higher values indicating a higher risk of the patient having cancer.

2.6. Limitations

- The PinPoint Urol Test must not be used for patients outside the intended use (individuals younger than 18 years old), as the product is not validated for these patients. The predictions generated would therefore be of unknown applicability and would pose a risk to patient safety.
- Measurements taken on blood specimens obtained via draw methods different from those described in this document have not been evaluated.
- Some analytes used by the PinPoint Urol Test are not unique to urological cancers, and as such the test may be sensitive to cancers beyond urological cancer, including cancers located in other sites of the body.

2.7. Warnings & Precautions

- Input values to the PinPoint Urol Test must be correct. The output of the product is highly reliant on the measurement values supplied as part of the request, and it is therefore of crucial importance that these values are accurate. Providing estimated or altered test inputs to the PinPoint Urol Test may generate inaccurate results. Laboratories performing data collection should hold accreditation to ISO 15189:2012, or similar as required by the Health Organisation.
- The PinPoint Urol Test must not be used multiple times on the same patient within a short time frame with the intent of obtaining a "desired" result.
- Test inputs must be obtained via measurement of a single blood sample taken specifically for the PinPoint Urol Test.

Use of pre-existing, historical measurements in the PinPoint Urol Test instead of analysing a contemporary blood sample may generate inaccurate results, and may not reflect the current physiological state of the patient.

- Test inputs must be provided in the specified units of measure for each analyte. See Appendix B for details.
- Any clinical threshold for the PinPoint Urol Test must be determined appropriately by the health organisation.
  Incorrectly set clinical thresholds may result in incorrect recommendations being made, and hence may lead to patient harm.
- The model used by the PinPoint Urol Test is fixed and will not adjust if the incoming patient population changes. If the patient population changes to a large extent, the product may no longer be validated for the population, which would pose a risk to patient safety.
  If it is suspected that the patient population has or will change, contact PinPoint Data Science to discuss the issue.

2.8. Performance Characteristics

The performance characteristics of the PinPoint Urol Test are listed in the table below with 95% confidence intervals in parentheses.

	Performance using clinical threshold providing:		
Performance Metric	15% rule-out	20% rule-out	90% rule-in
AUC	0.746 (0.700 - 0.793)	0.746 (0.700 - 0.793)	0.746 (0.700 - 0.793)
Sensitivity	1.000 (0.963 - 1.000)	1.000 (0.963 - 1.000)	0.897 (0.827 - 0.942)
Specificity	0.152 (0.121 - 0.188)	0.200 (0.166 - 0.239)	0.373 (0.329 - 0.418)
NPV	1.000 (0.937 - 1.000)	1.000 (0.952 - 1.000)	0.932 (0.883 - 0.962)
Threshold Test Value	23.3	35.7	108.5

The above was determined following performance evaluation using clinically representative retrospective data.

- "15% rule-out" refers to use of the test to identify patients with low PinPoint Urol Test Risk Scores, such that 15% of all patients tested will have a PinPoint Urol Test Risk Score lower than the threshold.
- "20% rule-out" refers to use of the test to identify patients with low PinPoint Urol Test Risk Scores, such that 20% of all patients tested will have a PinPoint Urol Test Risk Score lower than the threshold.
- "90% rule-in" refers to the use of the test to identify patients with high PinPoint Urol Test Risk Scores, such that 90% of patients with urological cancer who are tested will have a PinPoint Urol Test Risk Score higher than the threshold.

2.9. Requirements for Intended Users

For persons setting up the PinPoint Urol Test

- Relevant experience in health organisation IT infrastructure

For persons determining clinical thresholds

- Clinical thresholds should be determined by persons with knowledge of public health management, health economics, and Health Organisation targets, as well as knowledge of cancer symptoms, relevant cancer referral guidelines, and the interpretation of blood tests which can indicate increased risk of cancer

For persons using the PinPoint Urol Test for clinical decision making

- Clinical users are expected to have knowledge of cancer symptoms, relevant cancer referral guidelines, and the interpretation of blood tests which can indicate increased risk of cancer

3. Prior to Using the Test

3.1. Product Setup

Procedure for Health Organisation IT

The PinPoint Urol Test functions as a virtual send-away test. The test result is generated by the PinPoint algorithm (hosted by PinPoint Data Science), which uses blood analytes and additional clinical information, such as age and sex. No special software deployment is needed within the lab systems, but some configuration of existing systems is required.

For any issues or queries during setup or operation, please contact your PinPoint Data Science representative.

1. Select the appropriate connection method

   There are two methods supported for integrating PinPoint Urol Test into pathology systems: “Unsolicited Results” and “Solicited Results”.
   The "Unsolicited Results" method is generally preferred, but may not be supported by your LIMS. Consult with your PinPoint Data Science representative to determine the most suitable method for your system.

   For information on supported methods, please refer to Appendix A.

   If neither of the methods described are suitable for your system, please contact your PinPoint Data Science representative to discuss what other options are available.

2. Check IT infrastructure compatibility

   a. **HL7 messaging capability** – Ensure your LIMS can send and receive HL7 v2 messages, either directly or via X-Lab's Labgnostic system (formerly NPEx).

   b. **Labgnostic Integration (Labgnostic connection)** – If using Labgnostic, set up the necessary configurations to facilitate communication through this platform.

c. **Firewall Settings (direct connection)** – If required, adjust firewall and security settings to allow secure data exchange with external systems.

3. Configure the PinPoint Urol Test in your LIMS

   a. Add the PinPoint Urol Test as a send-away test in your LIMS, assigning the appropriate test codes according to your local policies.

   b. Add any analyte mappings required.

   c. Configure your system to request, receive, and correctly handle the results returned from the PinPoint Urol Test based on your selected connection method.

When configuring your system to request this test, ensure it sends only the analytes listed in Appendix B. No other inputs should be transmitted.

4. Inform and train relevant staff on the new processes involved with the PinPoint Urol Test.

Special characters which occur in HL7 messages returned by the PinPoint Urol Test will be escaped in accordance with the HL7 specification. For example, the | character shall be represented as the escape sequence \F\.
The consequences of this include:

- If a configuration option is set so that an HL7 field would contain a special character, the special character is represented as an escape sequence; and,
- If an error message returned by the test contains a special character, such as a backslash in a file path, then this shall be represented as an escape sequence.

5. Connection Verification

PinPoint Data Science provides verification data which can be sent to the PinPoint Urol Test to check that the connection is functioning correctly and connected to the correct PinPoint Test.
Please contact your PinPoint Data Science representative for the most recent set of verification data before performing verification of the connection.

Always request the most recent verification data from PinPoint Data Science before testing the connection. Using out-of-date verification data may lead to the connection incorrectly failing verification

3.2. Determining Clinical Thresholds

Procedure for persons or groups responsible for determining clinical thresholds

Clinical thresholds should be determined by persons with knowledge of public health management, health economics, and Health Organisation targets, as well as knowledge of cancer symptoms, relevant cancer referral guidelines, and the interpretation of blood tests which can indicate increased risk of cancer.

As with any such test, a clinical threshold can be chosen to separate those patients whose test results suggest they are more likely to be part of a normal population (below the clinical threshold), from those patients who are at higher risk of having cancer (above the clinical threshold).

The normal population is therefore defined by the choice of threshold, in a given clinical context.

The choice of clinical threshold will trade off sensitivity vs specificity, with the optimal choice depending on clinical context and any real-world factors that may apply.

Information on diagnostic accuracy performance of the test at various clinical thresholds is given in section 2.8 Performance Characteristics.

Any clinical threshold for the PinPoint Urol Test must be determined appropriately by the health organisation. Incorrectly set clinical thresholds may result in incorrect recommendations being made, and hence may lead to patient harm

The model used by this device is fixed and will not adjust if the incoming patient population changes. If the patient population changes to a large extent, the device may no longer be validated for the population, which would pose a risk to patient safety.
If it is suspected that the patient population has or will change, contact PinPoint Data Science to discuss the issue.

4. Test Procedure

Procedure for clinicians

4.1. Requesting a Test

1. Determine if patient symptoms and age make them eligible for the PinPoint Urol Test
2. Obtain a venous blood sample from the patient

Test inputs must be obtained via measurement of a single blood sample taken specifically for the PinPoint Urol Test.

Use of pre-existing, historical measurements in the PinPoint Urol Test instead of analysing a contemporary blood sample may generate inaccurate results, and may not reflect the current physiological state of the patient

3. Send the patient blood sample to your assigned pathology laboratory

Input values to the PinPoint Urol Test must be correct. The output of the device is highly reliant on the measurement values supplied as part of the request, and it is therefore of crucial importance that these values are accurate. Providing estimated or altered test inputs to the PinPoint Urol Test may generate inaccurate results.

Laboratories performing data collection should hold accreditation to ISO 15189:2012, or similar as required by the Health Organisation.

4.2. Sample Testing Requirements

Your pathology laboratory must perform a number of measurements to determine the levels of 30 analytes in the sample. The results must be provided in the applicable units within the intervals required for the test.

See Appendix B for a list of required analytes, supported units of measure, and accepted intervals for each unit of measure.

Your pathology laboratory must also provide the following patient information:

Information	Accepted Values	Comments
Date of Birth	N/A	Date of Birth must be provided in the appropriate HL7 format. Date of Birth must indicate a patient age between 18 and 125 years.
Sex	{F, M}	N/A

Test inputs must be provided in the specified units of measure for each analyte.
See Appendix B for details.

Test inputs must be provided within the defined accepted interval for each analyte and unit of measure.
Invalid test inputs will result in the test not being processed, and an error will be returned.
See Appendix B for details.

4.3. Receiving a Test Result

The PinPoint Urol Test will analyse the received information and generate a result which is returned through existing test management system infrastructure.

The returned result will contain the following information:

- PinPoint Risk Score
    - This will be in the interval 1 – 2000.
- Informational text
    - This will describe what a PinPoint Risk Score means and how the result should be used. This text is standardised for all results and does not vary between results.

The PinPoint Urol Test must not be used multiple times on the same patient within a short time frame with the intent of obtaining a “desired” result.

5. Customer Services

For product inquiries and technical support, please contact PinPoint Data Science by email at Support@PinPointDataScience.com.

If a serious incident or safety event relating to the use of this product has occurred, please contact PinPoint Data Science at Incidents@PinPointDataScience.com, as well as reporting the event to the UK Medicines & Healthcare products Regulatory Agency (MHRA).

6. Compliance

6.1. Legal

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Intellectual Property

For information on PinPoint Data Science Intellectual Property, please email Support@PinPointDataScience.com.

6.2. Regulatory

This product is an *in vitro* diagnostic medical device

PinPoint_Urol

PinPoint Data Science hereby declares that the product complies with all applicable UK regulations at the time of placing on the market.

The Declaration of Conformity to the UK Medical Devices Regulations 2002 (SI 2002 No. 618, as amended) can be found online at www.pinpointdatascience.com.

The PinPoint Urol Test is designed, developed and released by PinPoint Data Science Ltd.

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Appendices

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Appendix A. Connection Methods

Method 1: Unsolicited Results

1. **Initial Test Request** – Send a test request for the PinPoint Urol Test either via Labgnostic (formerly NPEx) or directly to PinPoint Data Science.
2. **Sending Analyte Results** – Send the required analyte results as unsolicited results following your initial request.
3. **Receiving Results** – Once all required results are received, PinPoint Data Science will return the PinPoint Urol Test result to your lab, linked to the initial request.

Method 2: Solicited Results

1. **Initial Test Request –** Send a test request for the PinPoint Urol Test to PinPoint Data Science through Labgnostic (formerly NPEx).
2. **Analyte Requests from PinPoint Data Science –** Labgnostic will send requests to your LIMS for the specific input analytes needed.
3. **Responding with Results –** Provide the requested analyte results in response to these requests.
4. **Receiving Final Result –** After all expected results are received, PinPoint Data Science will return the PinPoint Urol Test result linked to the initial request.

Appendix B. Test Analytes

The PinPoint Test can support multiple units of measure. Please contact PinPoint Data Science for alternate units if required.

Number	PinPoint Analyte ID	Analyte	Units	Accepted Interval
1	PHB	Haemoglobin level	g/L	25 - 250
2	PWBC	WBC count	10^9/L	0 - 1000
3	PRBC	RBC count	10^{12}/L	0.5 - 20
4	PNEU	Neutrophil count	10^9/L	0 - 200
5	PPLT	Platelet count	10^9/L	0 - 10,000
6	PMCV	MCV	fL	25 - 500
7	PLYM	Lymphocyte count	10^9/L	0 - 1000
8	PMONO	Monocyte count	10^9/L	0 - 100
9	PBASO	Basophil count	10^9/L	0 - 20
10	PEOS	Eosinophil count	10^9/L	0 - 50
11	PHCT	Haematocrit	L/L	0 - 1
12	PRDW	RDW	%	0 - 100
13	PCRP	CRP level	mg/L	0 - 10,000
14	PNA	Sodium level	mmol/L	10 - 1000
15	PPK	Potassium level	mmol/L	0.1 - 100
16	PCR	Creatinine level	µmol/L	0 - 10,000
17	PUREA	Urea level	mmol/L	0 - 1000
18	PBILI	Bilirubin level	µmol/L	0 - 10,000
19	PALT	ALT level	U/L	0 - 10,000
20	PALP	Alkaline Phosphatase level	U/L	0 - 20,000
21	PALB	Albumin level	g/L	0 - 1000
22	PCAM	Calcium level	mmol/L	0 - 100
23	PPHOS	Phosphate level	mmol/L	0 - 100
24	PCA125	CA125 level	kU/L	0 - ∞
25	PCA199	CA19-9 level	kU/L	0 - ∞
26	PCEA	CEA level	µg/L	0 - ∞
27	PCA153	CA15-3 level	kU/L	0 - ∞
28	PPSA	PSA level	µg/L	0 - ∞
29	PAFP	AFP level	kU/L	0 - ∞
30	PHCG	HCG level	IU/L	0 - ∞

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