EndoSign® capsule sponge test user guide

1. Purpose and scope

This user guide is intended to support healthcare professionals in the safe, accurate, and clinically appropriate use of the capsule sponge device for upper gastrointestinal sample collection. It provides detailed instructions and information to ensure that activities are performed correctly to avoid compromising sample integrity and conducted in a manner that prioritises patient safety.

The following products are required in order to carry out the procedure to collect a capsule sponge sample:

- **EndoSign® Cell collection device** (ES-CYT-102) – required to collect the capsule sponge sample
- **EndoSign® Cell preservation kit** (ES-CYT-101) – required to store and transport the capsule sponge sample

2. Limitations of use

As with any diagnostic test, test performance is determined by several factors, such as the quality of the patient samples collected. Strictly adhering to the procedure defined in this user guide for preservation, storage and shipping will ensure the quality of the oesophageal cell sample is sufficiently maintained.

The EndoSign® Cell preservation kit is for use in conjunction with the EndoSign® Cell collection device. The kit cannot be used for other sample collection devices and sample types. To be accepted into the laboratory for processing and analysis, all samples must be placed in the EndoSign® Cell preservation kit.

In addition to reading this user guide, healthcare professionals conducting the procedure must have completed the relevant training and follow good medical practice when collecting any samples.

3. Contraindication, precautions and warnings

For all contraindications of using the EndoSign® cell collection device and, precautions and warnings, refer to the Instructions for Use (IFU) for the following products, found within the device boxes and the online training platform:

- EndoSign® Cell preservation kit – ES-CYT-101
- EndoSign® Cell collection device – ES-CYT-102

4. Pre-clinic checks

Before sample collection, the patient must not have eaten for four hours prior to the procedure. Additionally, the following checks should be carried out:

- There are no contraindications of using the device - see the contraindications section on the instructions for use leaflet provided with the device
- Appropriate consent has been obtained from the patient to carry out the procedure

EndoSign® is a product and trademark of Cyted Health Ltd.
Cyted Ltd. Registered in England & Wales. Company #15199818.

Registered address: Ground Floor, Building 3 Old Swiss. 149 Cherry Hinton Road. Cambridge, CB1 7BX

- There are no defects or cracks in the capsule
- There is approximately 40ml of preservative in the cell preservation kit
- The cell preservation receptacle lid screws and unscrews correctly
- The EndoSign® cell collection device and the cell preservation kit are within their expiry date

If either device is unusable or expired, discard the devices in accordance with applicable local waste regulations.

Where any issues or defects are noted in either device, inform quality@cytedhealth.com and include device lot numbers and, if possible, provide any pictures that highlight the issue.

5. Collecting the sample

For guidance on administering the capsule sponge device to collect an oesophageal sample and the use of the preservation kit to store the sample, please refer to the product-specific Instructions for Use (IFUs) which can be found in the device packaging.

6. Sample labelling

To ensure unequivocal identification of the patient, the identity of the patient must be verified prior to sample collection.
Samples must be correctly labelled and accompanied by a fully completed Test Requisition Form (TRF) for the laboratory to accept them for processing and cytological analysis. If there is any mismatch or missing information between the sample and the TRF, Cyted's Service Team will contact the requesting site to obtain clarification. Where patient identifiers need to be confirmed, communication will be via a secure NHSmail account. See sections 7 and 8 below on how to complete the sample label and TRF.

The following patient details must be provided as minimum criteria for sample identification:

	EndoSign® Cell preservation kit label	**Test Requisition Form**
Mandatory	• Date of birth • Medical Record No. i.e. NHS/CHI/hospital number or equivalent • (Pot identifier, i.e. 25PXXXXX)	• Date of birth • Medical Record No. i.e. NHS/CHI/hospital number or equivalent • (Pot identifier, i.e. 25PXXXXX)
Optional	• Patient name (optional but recommended) • Sex	• Patient name (optional but recommended) • Sex

Any unlabelled EndoSign® Cell preservation kits will not be accepted for processing; a report will be issued detailing the reason for sample rejection.

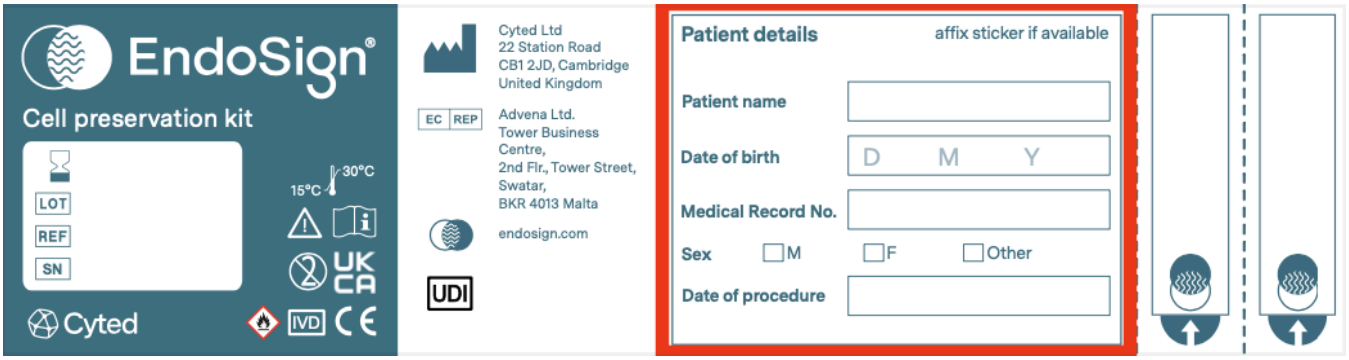
EndoSign® is a product and trademark of Cyted Health Ltd.
Cyted Ltd. Registered in England & Wales. Company #15199818.

Registered address: Ground Floor, Building 3 Old Swiss. 149 Cherry Hinton Road. Cambridge, CB1 7BX

7. Completing the EndoSign® Cell preservation kit label

Please note that all details on the EndoSign® cell preservation kit(sample) must match those on the test requisition form.

Complete the patient details section (highlighted below): date of birth, medical record number (e.g. NHS/CHI/hospital number), sex(where provided) and the date of procedure.
Note: If available, a sticker containing the required patient information can be affixed to this section



8. Completing the Test Requisition Form (TRF)

8.1. Types of TRF

There are two versions of the Test Requisition Form:

- Reflux TRF
  - To be used for patients with **chronic reflux**
- Barrett's oesophagus surveillance TRF
  - To be used for patients with **Barrett's oesophagus**

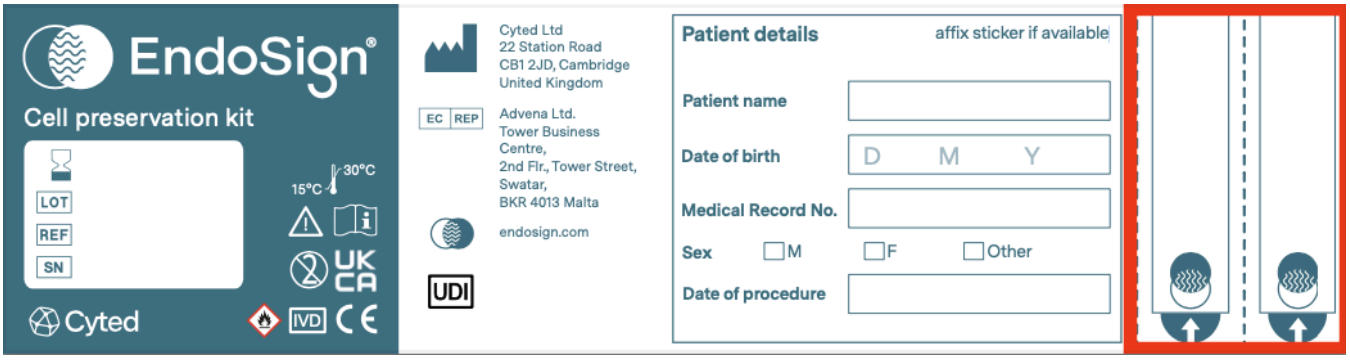
Each form has two formats: you can either complete the form by hand or complete an on-screen, interactive version and then print it out to add device ID stickers. The latest copies of the TRFs can be found on the website www.endosign.com under 'Providers' and 'Resources'**.**

All sections on the TRF are **mandatory** unless otherwise stated as **optional**.

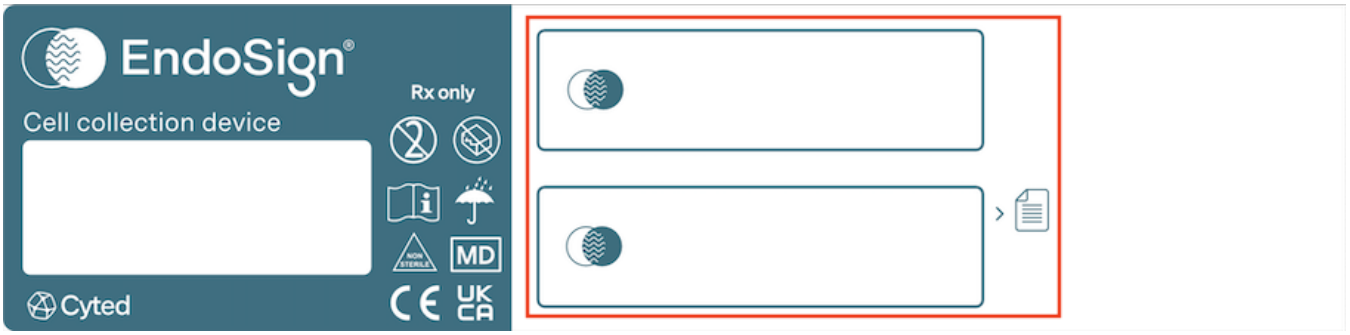
8.2. Device identifiers

Device identifiers are present as stickers on the labels of both devices. Remember to attach these device stickers to the TRF.

One peelable sticker (highlighted below) from the EndoSign® Cell preservation kit label should be stuck to section 5 of the Test Requisition Form and the second peelable sticker should be used for internal patient records.



One peelable sticker (highlighted below) from the EndoSign® Cell collection device label should be stuck to section 6 of the Test Requisition Form and the second peelable sticker should be used for internal patient records.



9. Laboratory processing and reporting

Laboratory processing and reporting of capsule sponge specimens are performed by two different laboratories:

- Laboratory processing of capsule sponge specimens(including all examination activities) is carried out at the Cyted UK Ltd laboratory located at 2 Falcon Road, Hinchingbrooke Business Park, Huntingdon, PE29 6FG.
- Diagnostic reporting of capsule sponge specimens is carried out by the Cyted Ltd laboratory located at Ground Floor, Build 3 Old Swiss, 149 Cherry Hinton Road, Cambridge, CB1 7BX.

The opening hours of both laboratories are 9am to 5pm Monday to Friday.

10. Accessing reports

All test reports can be accessed via Cyted Health's customer portal via this link. Once a report has been authorised, portal users will receive an email notification confirming that the result is ready to download. The email will include the relevant sample ID. If you experience any issues with the portal, please email service@cytedhealth.com with a description of the problem and screenshots where possible. Further details are available in the 'Contact Information' section below.

11. Storing samples

Store the cell preservation kit containing the cell collection device at room temperature. Do not freeze. Do not send samples for any failed attempts. A cell preservation kit containing a cell sample can be stored at room temperature for up to 28 days.

12. Packaging

1. Double-check that the lid of the EndoSign® Cell preservation kit is tightly closed, and the seal is not cross-threaded. This will prevent leaks during transport.
   NOTE: Any high-risk samples must be marked as such using a high-risk sticker on both the sample and TRF.
2. Place the EndoSign® Cell preservation kit inside the biohazard bag provided with the absorbent pad.
3. Remove the tape strip and fold over to seal the biohazard bag.
4. Place the folded Test Requisition Form (completed and with matched patient ID) in the back pocket of the biohazard bag. To avoid contamination, do not place the TRF in the same pocket as the sample.
5. Package up to five sealed biohazard bags into each pre-labelled courier return box. This pre-labelled courier box meets the relevant requirements to transport specimens, therefore other boxes not provided by Cyted must not be used for transport.
6. Affix the security seal to the outside of the courier return box. Ensure that the shipping label and UN identifiers are not obscured.

13. Shipping

1. As you package the samples for shipping, complete the online shipping record form (https://forms.gle/2CuQYJSr9kAbGUNZ6) to record the number of samples and boxes that are being collected.

2. Check that the shipping label and UN identifier are not modified or obscured.
3. Move all packaged samples ready for courier collection to the designated collection point outlined in your clinic-specific Site Set Up Form.
4. Ensure that all samples are handed **in person** to the assigned courier.
   NOTE: If applicable, verify the courier's identification and provide name and signature on collection
5. The team at service@cytedhealth.com will confirm receipt of the samples via email

14. Placing an order for more devices

Cyted requires a purchase order in place before any EndoSign devices can be delivered. If you have an open purchase order and need more devices or courier return boxes then please complete the order request form (https://forms.gle/NofGMidHCBNq72nGA). This form should be completed 14 days in advance of the requested delivery date.

15. Turnaround times

The turnaround time for reporting capsule sponge samples is 14 business days.

EndoSign® is a product and trademark of Cyted Health Ltd.
Cyted Ltd. Registered in England & Wales. Company #15199818.

Registered address: Ground Floor, Building 3 Old Swiss. 149 Cherry Hinton Road. Cambridge, CB1 7BX

16. Contact information

The Cyted team is available Monday to Friday, 9am to 5:30pm (UK time), and can be contacted via the email addresses below:

- service@cytedhealth.com - for general any queries relating to the service or any IT issues. This email address must not be used to send personally identifiable information(PII). For urgent matters requiring immediate attention, please add 'urgent' to the email subject line.
- cyted.lab.enquiries@nhs.net.- Any queries containing any personally identifiable information (PII) such as patient names or record numbers
- quality@cytedhealth.com - for any serious incidents relating to the EndoSign® devices or any complaints about the service
- For clinical advice relating to the examination or the interpretation of examination results, please contact the team service@cytedhealth.com who will direct your query to the appropriate person.

These mailboxes are staffed during UK working hours. In the unusual circumstances where support is not being provided for high severity issues in a timely manner then users may request escalation of the issue through the service@cytedhealth.com channel.

In the interest of data protection, emails to non-NHS addresses should only contain pseudoanonymised data.

17. Clinical Guidance

Clinical guidance documents for Barrett's surveillance and reflux patients are available at request from Cyted.

18. Data Protection

Cyted ensures the safeguarding and appropriate treatment of patient samples which includes data handling and confidentiality. Our privacy policy can be found on our website cytedhealth.com/privacy

EndoSign® is a product and trademark of Cyted Health Ltd.
Cyted Ltd. Registered in England & Wales. Company #15199818.

Registered address: Ground Floor, Building 3 Old Swiss. 149 Cherry Hinton Road. Cambridge, CB1 7BX