

## **RightSpotpH Small Bore Indicator**

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### **PURPOSE**

The RightSpotpH<sup>®</sup> Small Bore Indicator is an in vitro diagnostic pH test device for the evaluation of gastric acidity. It consists of a closed inline system for specimen acquisition, testing, result determination, and disposal. For convenience and to prevent cross-contamination it also provides an on-device pH Reference Key. Unique protective single-unit packaging prevents air, light, and humidity from affecting the integrity of the pH paper contained within the device. It is intended to verify initial placement of any tube intended to end in the stomach; thus ruling out misplacement. It is also intended to verify correct placement of any tube intended to end in the stomach by ruling out displacement of any existing tube. A resulting pH of 5.5 or below indicates gastric acidity and therefore placement in the stomach.

### **METHODOLOGY/PRINCIPLE**

The RightSpotpH<sup>®</sup> Small Bore Indicator is connected to a syringe containing a specified amount of air and then is attached to the proximal end of a tube whose distal end is desired to end in the stomach. After instilling the air bolus aspirate is drawn up through the tube and into the Indicator thus saturating the pH paper inside the Indicator. This saturation occurs behind the pH paper so aspirate, regardless of opaqueness or color, does not obscure the color change. The color change of the pH paper is readily observed and compared to the pH Reference Key on the shaft of the Indicator to obtain a pH reading. A pH reading less than or equal to 5.5 is indicative of correct placement in the stomach. A pH reading greater or equal to 6.0 warrants further investigation as to the cause of the higher reading. Do not deliver any fluids into a tube until determination of its tip location is confirmed to be in the stomach.

### **SPECIMEN COLLECTION/REQUIREMENTS**

Acceptable specimens are aspirate collected from an NG tube or other tubing intended to be placed in stomach.

### **SAFETY**

All samples are potentially infectious and must be handled in accordance with established safety policies. See RELATED DOCUMENTS section.

See REAGENTS Section for listing of any hazardous chemicals.

### **EQUIPMENT**

The RightSpotpH<sup>®</sup> Small Bore Indicator (for use with tubes 10 French or smaller in diameter). Enteral Syringe (8 ml or larger). Optionally the RightSpotpH<sup>®</sup> Indicator (intended for use with tubes larger than 10 French). Optionally the RightSpotpH<sup>®</sup> Small Bore ENFit<sup>®</sup> (for connecting to ENFit<sup>®</sup>-style tubes and syringes).

### **MAINTENANCE**

NA

### **REAGENTS AND REAGENT PREPARATION**

Carolina Biological Supply Clear pH 3.0 Buffer –Store at room temperature in cool dry place,  
Carolina Biological Supply Clear pH 7.0 Buffer – Store at room temperature in a cool dry place.  
Appropriate RightSpotpH<sup>®</sup> Indicator - Store devices at room temperature in a cool, dry place.  
Acceptable storage range is -50° F to 125°F as individualized Indicator packaging prevents exposure of pH paper inside each Indicator to damaging air, light, and humidity.

Type of Hazard: Irritant.

SDS on file for each chemical in the On-Line SDS Library.

For additional hazardous chemical safety information see RELATED DOCUMENTS.

### **METHOD PROCEDURE**

The RightSpotpH<sup>®</sup> Small Bore Indicator is used to verify initial placement of tubes intended to end in the stomach if an X-ray verifying proper stomach placement is not also being performed. The RightSpotpH<sup>®</sup> Indicator is also used to verify placement of existing tubes at least once per shift.

#### **Procedural Steps**

1. Verify the expiration date printed on the outer protective foil package of the RightSpotpH<sup>®</sup> Small Bore Indicator. Use ONLY if not expired.
2. Remove the Indicator from the packaging and examine the Indicator's internal pH paper. The internal pH paper should be a tan to olive green color – do not use if the Indicator strip is any other color.
3. The Indicator may be packaged with caps at both ends. If so remove any caps from the ends of the Indicator and discard.
4. Attach an enteral syringe to the bottom end of the RightSpotpH<sup>®</sup> Small Bore Indicator and pull up 1.0 – 3.0 ml of air.
5. Attach the top end of the RightSpotpH<sup>®</sup> Small Bore Indicator to the proximal end of the tube.
6. Insufflate air into the stomach by pressing down on the syringe plunger. This step clears the tube of fluids and pushes the tube tip away from the wall of the stomach.
7. Slowly pull back on the syringe to aspirate fluid while observing the Indicator's pH paper. Completely saturate the Indicator's pH paper with fluid and stop aspirating once the Indicator pH paper changes color. The test is not valid if a color change is not observed. Do not push aspirate back through the Indicator.
8. Compare the color change on the Indicator's pH paper to the Reference Key encircling the device shaft. Record the numeric pH reading that corresponds to the matching color change observed on the Indicator's pH paper.
9. Carefully remove the RightSpotpH<sup>®</sup> Small Bore Indicator from the tube and discard the Indicator device and the attached syringe into a SHARPS or biohazard waste container. Do not attempt to remove the Indicator device from the syringe before disposing.

**TO RECHECK GASTRIC PLACEMENT OF EXISTING TUBE:**

Bolus Feed

1. Test prior to or wait 20-30 minutes after giving a bolus feed so the stomach may re-acidify.
2. Using an 8 ml or larger enteral syringe first clear the tube with AIR. If clearing line with water, it is important to then clear the entire length of the feeding tube with AIR. If water or feeding supplement is left in the tube it will alter the pH reading. The amount of air to instill should be greater than the prime volume of the tube as determined by the clinician.
3. Gather one RightSpotpH<sup>®</sup> Small Bore Indicator and one enteral syringe (8 ml or larger). Verify the expiration date printed on the outer wrapper of the RightSpotpH<sup>®</sup> Small Bore Indicator. Use ONLY if not expired.
4. Pull back on the enteral syringe to 1.0 – 3.0 ml. The amount of air to instill should be greater than the prime volume of the tube plus an additional 0.5 ml as determined by the clinician.
5. Attach the RightSpotpH<sup>®</sup> Small Bore Indicator to the syringe on one end and to the tube on the other end.
6. Insufflate the air into the stomach to clear the tube of liquids and to remove the tip of the tube from the stomach wall.
7. Aspirate enough stomach contents into the Indicator to saturate the entire pH paper within the device and observe for a color change. Stop aspirating once the Indicator's pH paper changes color. If a color change is not observed, the test is invalid.
8. Compare the color change on the Indicator's pH paper to the Reference Key encircling the device shaft. The result must be read within 2 minutes to be valid.
9. Record the numeric pH reading from the Reference Key that corresponds to the matching color change observed on the Indicator's pH paper. Document numeric result under the POCT pH parameter.
10. If aspirate is not obtained, position the patient in the left lateral recumbent position, if tolerable, and reattempt in approximately 10 minutes.

Continuous Feeding

1. Turn off the feeding supplement. Wait 20-30 minutes after stopping feed so the stomach may re-acidify.
2. Using an 8 ml or larger enteral syringe first clear the tube with AIR. If clearing line with water, it is important to then clear the entire length of the feeding tube with AIR. If water or feeding supplement is left in the tube it will alter the pH reading. The amount of air to instill should be greater than the prime volume of the tube as determined by the clinician.
3. Gather one RightSpotpH<sup>®</sup> Small Bore Indicator and one enteral syringe (8 ml or larger). Verify the expiration date printed on the outer wrapper of the RightSpotpH<sup>®</sup> Indicator. Use ONLY if not expired.
4. Pull back on the enteral syringe to 1.0 – 3.0 ml. The amount of air to instill should be greater than the prime volume of the tube plus an additional 0.5 ml as determined by the clinician.
5. Attach the RightSpotpH<sup>®</sup> Small Bore Indicator to the syringe on one end and to the tube on the other end.

6. Insufflate the air into the stomach to clear the tube of liquids and to remove the tip of the tube from the stomach wall.
7. Aspirate enough stomach contents into the Indicator to saturate the entire pH paper within the device and observe for a color change. Stop aspirating once the Indicator's pH paper changes color. If a color change is not observed, the test is invalid.
8. Compare the color change on the Indicator's pH paper to the Reference Key encircling the device shaft. The result must be read within 2 minutes to be valid.
9. Record the numeric pH reading from the Reference Key that corresponds to the matching color change observed on the Indicator's pH paper. Document numeric result under the POCT pH parameter
10. If aspirate is not obtained, position the patient in the left lateral recumbent position, if tolerable, and reattempt in approximately 10 minutes.

### Trouble Shooting

If unable to obtain aspirate, observe the incremental marking on the tube at the exit site or measure the external tube length and compare it to the incremental marking or external tube length as recorded at time of insertion. Determine if tube has moved from original placement and consider steps to rectify as needed. Next clear the line with air and turn patient on left side for 10 minutes and retest.

If pH is  $\geq 6$  and the patient is on gastric acid blocking medications, proceed to confirming tube placement by the incremental marking on the tube or by performing an X-ray intended to confirm placement of a tube in the stomach.

If patient is experiencing any unexplained respiratory distress, gagging, vomiting, or irritability do not use the tube. Consult the LIP to consider next steps including possible tube replacement.

### Quality Control

Two levels of quality control are performed with each new lot of RightSpotpH<sup>®</sup> Indicators and with each new shipment received before releasing the Indicators for clinical use. Additionally, QC is performed once a month on stocks of in-use devices. If stocks are stored in a central location then take two devices from the central storage supply to perform QC. If stocks are stored throughout a unit, such as in cabinets in patient rooms, take two devices from two different storage locations to perform QC, rotating through different locations each month. Buffer solutions with a pH of 3.0 and 7.0 are used for the two controls.

### Procedural Steps

1. Gather two RightSpotpH<sup>®</sup> Indicators, one pH 3.0 buffer solution and one pH 7.0 buffer solution, two syringes 3 ml or larger, and the RightSpotpH<sup>®</sup> Indicator QC log sheet.
2. Verify the expiration dates on the RightSpotpH<sup>®</sup> Indicators and the pH buffers.
3. If the RightSpotpH<sup>®</sup> Indicators are a new lot then start a new QC log, recording the lot numbers and expiration dates of the RightSpotpH<sup>®</sup> Indicators and QC buffers on the log.
4. If either of the pH buffer solutions are a new lot, document in the Comments section of the log the pH buffer level and lot number.
5. Remove the RightSpotpH<sup>®</sup> Indicator from its packaging. If the device is packaged with end caps, remove the end caps.
6. Examine the internal pH paper as it should be a tan to olive green color – do not use if the Indicator strip is any other color.

7. Attach a syringe to the end of the RightSpotpH<sup>®</sup> Indicator.
8. Pour a small amount of one of the buffer solutions into the cap of the solution bottle or other secondary container.
9. Place the end of the RightSpotpH<sup>®</sup> Indicator into the poured off buffer solution and pull back on the syringe, aspirating the buffer solution into the RightSpotpH<sup>®</sup> Indicator device. Do not attempt to pull solution directly from the bottle of pH buffer solution.
10. Observe the pH paper inside the RightSpotpH<sup>®</sup> Indicator and stop aspirating as soon as the pH paper changes color.
11. Record the pH reading from the reference chart corresponding to the color of the RightSpotpH<sup>®</sup> Indicator's pH paper onto the QC log
12. Repeat procedure with the remaining pH buffer solution. BOTH must pass for validation.

### **RESULT REPORTING**

Document the RightSpotpH<sup>®</sup> Indicator result in the EMR under the POCT parameter.

### **Interpretation/Reporting Procedure**

A pH  $\leq 5.5$  indicates correct placement in stomach

A pH reading of 6.0 may indicate the aspirate may be contaminated with food, medications, or water, or it may indicate incorrect placement of the tube outside of the stomach. A pH greater or equal to 6.0 requires further investigation as to the cause of the higher reading. Do not deliver any fluids into a tube until determination of its tip location is confirmed to be in the stomach.

### **Interferences**

PPI or H2 Blockers, water, food, or grossly bloody samples can all elevate the pH reading of gastric aspirates. Patients on PPI or H2 Blockers should be tested PRIOR to medication administration or wait approximately 2 hours before testing so that the stomach may re-acidify. Do not test if the sample is grossly bloody. However dried or coagulated blood in aspirate that produces a coffee grounds appearance will not interfere with the RightSpotpH<sup>®</sup> test.

### **Limitations**

The RightSpotpH<sup>®</sup> Indicator can detect a pH range from 4.5-7.0.

### **Reference Ranges**

Gastric Aspirate 1.5 –5.5

### **Critical Results**

NA

### **TEST ANALYTICS**

Linearity, precision, accuracy, sensitivity, specificity and other analytical information is on file in laboratory area.

### **BACK UP TESTING**

An X-ray intended to confirm placement of a tube in the stomach.

Observing the incremental marking on the tube at the exit site or measuring the external tube length and comparing it to the incremental marking or external tube length as recorded at time of insertion.

**RELATED DOCUMENTS**

Pathology Safety Manual

**REFERENCES**

RightSpotpH<sup>®</sup> Indicator Inservice Video DM05112021.mp4  
IFU RS001 RSSB001 RSEN001 Rev G  
NG Change of Practice 7.13.21