U.S. English

Product Number: 9549



for Histamine Quantitative Test

Store at room temperature (18–30°C)



Reveal® Q+ for Histamine

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Histamine

High levels of histamine may develop in a variety of fish species as they decompose. These species include tuna, mahi-mahi, marlin, bluefish, sardines, anchovy, bonito, herring, and mackerel. Ingestion of histamine may cause scombroid poisoning in humans, which may lead to a variety of symptoms, including rash, nausea, vomiting, diarrhea, hypotension, heart palpitations, and muscle weakness. Paralysis and death have also been reported in cases of scombroid poisoning.

Because of its potential for human illness, the U.S. Food and Drug Administration (FDA) has ruled that extensive refrigeration records and/or histamine testing must be included in a hazard analysis and critical control point (HACCP) program for relevant fish species. The FDA has set an action level of 50 parts per million (ppm) for histamine in domestic and imported fish.

Intended Use

Reveal® Q+ for Histamine is intended for the quantitative analysis of histamine in scombroid species of fish, such as tuna, mahi-mahi, and dry fishmeal.

Intended User

The test kit is designed for use by quality control personnel and others familiar with histamine analysis in fish. Since technique is very important, operators should be trained by a Neogen® representative or someone who has completed Neogen training.

Assay Principles

Reveal Q+ for Histamine is a lateral flow immunochromatographic assay based on a competitive immunoassay format. The extract is wicked through a reagent zone, which contains antibodies specific for histamine conjugated to colloidal gold particles. If histamine is present, it will be captured by the particle-antibody complex. The histamine-antibody-particle complex then is wicked onto a membrane, which contains a zone of histamine conjugated to a protein carrier. This zone captures any uncomplexed histamine antibody, allowing the particles to concentrate and form a visible line. As the level of histamine in a sample increases, free histamine will complex with the antibody-gold particles. This, in turn, allows less antibody-gold to be captured in the test zone. Therefore, as the concentration of histamine in the sample increases, the test line density decreases. Algorithms programmed into the Raptor® reader convert these line densities into a quantitative result, displayed in ppm. The membrane also contains a control zone where an immune complex present in the reagent zone is captured by an antibody, forming a visible line. The control line will always form regardless of the presence of histamine, ensuring the strip is functioning properly.

Storage Requirements

Store kit components at room temperature (18–30°C, 64–86°F) to ensure full shelf life. Test strips should remain capped in their original sample tubes until used to ensure optimal performance.

Materials Provided

- 1. 25 histamine test strips
- 2. 25 red dilution cups
- 3. 1 bottle sample diluent

Materials Recommended but Not Provided

- 1. Graduated cylinder (Neogen item 9368)
- 2. Scale capable of weighing 10-50 g (Neogen item 9427)
- 3. Pipettor, 100 μL (Neogen items 9272, 9278, 9276)
- 4. Pipette tips (Neogen items 9410, 9407, 9417)
- 5. Pipettor, 1000 μL fixed (Neogen item 9337)
- 6. Pipette tips 100-1000 μL (Neogen item 9464, 9487)
- 7. Paper towels or equivalent absorbent material
- 8. Rack for Reveal sample cups (Neogen item 9475)
- 9. Timer (Neogen item 9426)
- 10. Waterproof marker
- 11. Distilled or deionized water
- 12. Sample extraction bottles, 250 mL (Neogen item 9399)
- 13. Sample collection tubes (Neogen item 9421)
- 14. Blender (Neogen item 9493, 9477)
- 15. Pipettor 400 μL, fixed (Neogen item 9693)
- 16. Raptor Integrated Analysis Platform (Neogen item 9680)
- 17. Raptor cartridges (Neogen item 9681)

Precautions

- 1. The test strips must remain inside the stay-dry tube before use.
- 2. Store test kit at room temperature (18-30°C, 64-86°F) when not in use.
- 3. Do not use kit components beyond expiration date.
- 4. Treat all used liquids, including sample extract, and labware as if contaminated with histamine. Gloves and other protective apparel should be worn at all times.
- 5. To avoid cross-contamination, use clean equipment for each sample, and thoroughly wash all equipment between samples.
- 6. Glassware should not be used for extraction purposes. Histamine may adhere to glass, therefore using glassware may affect test results.

Sample Preparation

Canned Tuna: AOAC 937.07b

Place entire contents of can/pouch (meat and liquid) into a blender. Blend until homogenous. Store samples at 2–8°C (35–46°F) until analyzed.

Fresh or Thawed Frozen Raw Fish: AOAC 937.07a

Clean and eviscerate three fish. Cut three cross-sectional pieces 2.5 cm (1 inch) thick, from back of the pectoral fin, halfway to the vent and one posterior to the vent. Debone slices and blend or grind combined samples until homogenous. Store samples at 2-8°C (35-46°F) until analyzed.

Dry Sample

The sample to be tested should be collected according to accepted sampling techniques and be representative of the lot. After homogenization, grind part of the sample (minimum of 200 g) so at least 95% of the ground material passes through a 20 mesh sieve.

Sample Extraction

- 1. Add 190 mL deionized water to a clean disposable extraction bottle.
- 2. Add 10 g of homogeneous sample.
- 3. Tightly cap and vigorously shake the bottle for 15-20 seconds to suspend the fish tissue in the water.
- 4. Wait approximately 5 minutes, and then shake the bottle for 15-20 seconds to resuspend the fish tissue.
- 5. Wait an additional 5 minutes, and again shake the bottle for 15–20 seconds to resuspend the fish tissue. Allow the tissue to settle to the bottom of the bottle for about 30 seconds. The sample is now ready for testing.

Dry Sample Extraction

- 1. Add 230 mL deionized or distilled water to a clean disposable extraction bottle.
- 2. Add 10 g of the dry sample to the bottle.
- 3. Tightly cap and vigorously shake the bottle for 15–20 seconds to suspend the sample in the water.
- 4. Wait approximately 5 minutes, then shake the bottle for 15–20 seconds to resuspend the sample.
- 5. Wait an additional 5 minutes, and again shake the bottle for 15–20 seconds to resuspend the sample. Allow the sample to settle to the bottom of the bottle for about 30 seconds. The sample is now ready for extract dilution.
- 6. If necessary, filter the contents using a histamine filter syringe (Neogen #9420H) into a clean container. **Alternative:** Centrifuge the sample and use the clear supernatant as the sample for testing.

Test Procedure

- 1. Place the appropriate number of red sample dilution cups in a sample cup rack. Label cups if necessary.
- 2. Add 100 µL of sample extract to each red sample dilution cup.
- 3. Add $1000 \, \mu L$ of sample diluent to red sample dilution cup. Mix by pipetting up and down 5 times.
- 4. Fully insert a Reveal Q+ for Histamine test strip into a Raptor cartridge.
- 5. Insert the Raptor cartridge containing the test strip into any of the three ports within the Raptor.
 - a. The barcode on the test strip will be read. The system identifies the type of test strip and the lot number. If the lot number is not found in the system, the barcode reader in the front of the Raptor will turn on automatically.
 - b. Scan the QR code found on the tube containing the test strips. The information will be stored on the reader.
- 6. Enter a sample ID if desired.
- Add 400 μL of sample extract from the red sample dilution cup to the Raptor cartridge.
 - a. The Raptor system will start automatically.
 - b. Additional samples can be started in the other ports while the first sample is processing.
- 8. Results will be displayed on the Raptor screen after the 5-minute testing period is complete.

Dilution Procedure

Samples greater than 40 ppm will need to be diluted and retested.

Example for 1:11 Dilution

- 1. Add 100 μL sample filtrate to a sample collection tube.
- 2. Add 1000 µL distilled or deionized water to the sample collection tube. Cap the tube and shake well.
- 3. Place a red dilution cup into the sample rack. Label cup as needed.
- 4. Add 100 μL diluted sample (from step 2) to the red dilution cup.
- 5. Add 1000 µL sample diluent to the red dilution cup. Mix well by pipetting up and down five times.
- 6. Fully insert a Reveal Q+ for Histamine test strip into a Raptor cartridge.
- 7. Insert the Raptor cartridge containing the test strip into any of the three ports within the Raptor.
- 8. Enter a sample ID if desired.
- 9. Press dilution.
- 10. Select dilution factor 1:11. Press next.
- 11. Add 400 µL of sample extract (from step 5) to the Raptor cartridge. The Raptor system will start automatically.
- 12. Results will be displayed on the Raptor screen after the 5-minute testing period is complete.

Note: The Raptor will calculate your result based on the dilution factor selected.

Note: If you did not activate the dilution factor, the result displayed must be multiplied by the dilution factor used, in this example, by 11.

Performance Characteristics

Limit of detection: 0.5 ppm Range of detection: 1.5–40 ppm

Note: Samples greater than 40 ppm must be diluted and retested.

Customer Service

Neogen Customer and Technical Services can be contacted through neogen.com and product training is available by request.

SDS Information Available

Safety data sheets are available for all test kits at neogen.com or by calling 800.234.5333 or 517.372.9200.

Terms and conditions

Neogen's full terms and conditions are available online.

Warranty

Neogen makes no warranty of any kind, either expressed or implied, except that the materials from which its products are made are of standard quality. If any materials are defective, Neogen will provide a replacement of the product. Buyer assumes all risk and liability resulting from the use of this product. There is no warranty of merchantability of this product, or of the fitness of the product for any purpose. Neogen shall not be liable for any damages, including special or consequential damage, or expense arising directly or indirectly from the use of this product.