Ruhof ATP® Complete Calibration Control Kit

Part Number: 345PCD I Contents: One Positive Rod: One Negative Rod Calibration Control Kit for verifying calibration of Ruhof’s ATP Complete Contamination Monitoring System

Description/Intended Use
The calibration control rods in this kit are intended to be used to verify calibration of the above luminometers. A Positive Rod consists of C14 radioactive source that emits very low level of low-energy βr radiation in a plastic scintillation matrix. The Matrix is configured to give constant light output, within 10% of its original value, at a sufficiently high level for up to five years. The Negative Rod is used to check for possible background light getting into the instrument or light detector. The Negative Rod produces low-light (0-4) RLU. It is recommended to verify calibration with the Calibration Control Kit every three months. Additionally, incorporating The Calibration Control Kit into your overall quality control program will validate the instrument is within specifications and operating correctly.

Shelf Life: Five (5) years as marked on Positive Rod.

Storage: Store at 15°-25°C (59°-77°F) in box rods were received in or dark container. Store away from light.

Directions for Use:
Positive and Negative Rods are inserted and read in luminometer in the same manner as ATP sample device. Calibrations rods do not need to be activated like the ATP sample device. Do not attempt to activate Positive or Negative Rod.

1. Open sample chamber and insert Positive Rod. Close lid. Let it sit for 1 minute.
2. Press “OK” and take reading as normal.
3. Record result. Repeat step 2 another two times and record results. Calculate the average of these three readings and enter it in the Positive Rod Reference No box below. Repeat step 1 through 3 for each luminometer being checked with this Positive Rod.
4. Repeat steps using Negative Rod.

<table>
<thead>
<tr>
<th>Positive Rod Reference No.</th>
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<tbody>
<tr>
<td>Instrument Serial Number</td>
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<tr>
<td>Test 1</td>
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<td>Test 2</td>
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<tr>
<td>Test 3</td>
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<tr>
<td>Average</td>
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Retain the Positive Rod Reference No.

Interpreting Positive and Negative Control Results
Positive Rod in a correctly calibrated Ruhof ATP Complete® luminometer should read between 40-80 RLU. The Positive Rod Reference No. should not vary by more than + 20%. If the results from the Positive Rod are outside the RLU range; or vary by ± 20% from the Positive Rod Reference No. then the machine should be sent in for service. Negative Rod should read between 0-4 RLU.

Incorporating the Calibration Control Kit into a Quality Control Program
Calibration Control Kit is designed to be incorporated into a Quality Control Program that monitors and tracks performance of Ruhof equipment and/or devices. When using calibration control rods to verify measurability of a luminometer; it is recommended that a specific program point (e.g. PROG 250) be assigned for results. All results can be viewed directly from luminometer or in the data analysis software.

Causes for Inconsistent Calibration RLU Readings
Several factors can cause RLU readings to be outside acceptable range. Possible causes are:

- Dirty or damaged calibration rods. Clean outside of both rods with lint-free doth that has been dipped in reagent-grade isopropyl or ethyl alcohol. Air dry and repeat reading.
- Luminometer contamination. Results that have changed suddenly, especially immediately after a number of sampling devices have been run, can indicate contamination problems. Results from calibration rods can increase or decrease as result of foreign materials disturbing optics chamber of instrument If contamination is suspected In the luminometer, remove read chamber and clean. See owners manuals on how to clean read chamber.
- Scratches on glass bottom do not affect readings.
- Exposure to light. Inconsistent readings arise if calibration rods are exposed to intense light prior to being read. Insert calibration rods into a luminometer and wait minimum of 2 minutes before taking reading.

Handling and Disposal
To ensure stability and longevity of calibration rods, take the following steps:

- Limit exposure to light. Store calibration rods in dark or weak ambient light. Kit box provided is recommended as appropriate dark storage. Do not expose to direct sunlight or intense artificial light for too long before use.
- Handle with care. Avoid crushing, cutting, or dropping calibration rods. Any damage that changes shape or light transmission properties of the Positive Rod can affect assigned values.
- Disposal. For U.S. and Canadian customers: Level of radioactive material in Positive Rod does not require special hazardous waste treatment, per U.S. Federal regulations governing use and transfer of exempted radioactive materials. The contents of the Positive Rod are exempt from NRC or Agreement State licensing requirements Positive Rod contains extremely small amounts of radioactive carbon-14. completely contained by the outer housing of the device. There are no radioactive emissions on the surface of the device, and no special precautions are needed in handling the device to avoid exposure, Positive Rod is designed for use and storage at room temperature; prolonged exposure to extreme heat or cold should be avoided. Do not use if the scintillator tip of the device is cracked or damaged.
- To dispose of Positive Rod, remove or deface “Caution Radioactive Materials” label on rod. Positive Rod may then be disposed of in trash. For disposal requirements in other countries check with your national and local supplier.
- Radioactive Material - Not for Human Use - Introduction into foods, beverages, cosmetics, drugs, or medicinal products, or into products manufactured for commercial distribution is prohibited. Exempt quantities should not be combined.

Manufactured for Hygiena by Isotope Products Laboratories

For more information on the ATP Complete® visit www.ruhof.com or call 1-800-537-8463

THE RUHOF CORPORATION 393 Sagamore Avenue, Mineola, New York 11501

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