

**ADVIA® 1200 Chemistry Systems**  
**ADVIA® 1800 Chemistry Systems**  
**ADVIA® 2400 Chemistry Systems**

#### Potential for Halogen Lamp Premature Failure (SMN 10309448)

Our records indicate that your facility may have received one of the affected products listed below.

**Table 1. Affected ADVIA Chemistry Products**

| Product    | Siemens Material Number (SMN)  |
|------------|--|
| ADVIA 1200 | 10309735, 10470358, Legacy Numbers – 094-A001-02, 094-A001-03, 094-A001-04, 094-A001-05, 094-A001-06 |
| ADVIA 1800 | 10315183, 10322655, 10337372, 10337373, 10337374, 10337375, 10337376                                 |
| ADVIA 2400 | 10315769, 10816871, 10816872, 10816873, 10816874, 10816875, 10816876                                 |

#### Reason for Customer Notification

Siemens Healthcare Diagnostics is issuing a Customer Notification for the ADVIA® Chemistry Halogen Lamp (SMN 10309448). Siemens has identified specific lot numbers of the Halogen Lamp, listed below, that may have a defect that could cause it to fail prematurely.

Affected Lots:

J411, J412, J501, J502, J503, J504, J505, J506

#### Risk to Health

The potential exists for a delay in testing if the Halogen Lamp fails prematurely. Results are not impacted as the system will become inoperable when this issue occurs. The risk to health is negligible. Siemens is not recommending a laboratory look back as a result of this issue.

#### Actions to be Taken by the Customer

For the products listed in Table 1, please perform the following steps:

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- Please check your inventory for affected lots, see Fig 1 and 2 for the location of lot information on the packaging and product, respectively.
  - Note: If your current inventory includes any lamps from the affected lot numbers that have a green dot on the packaging (see Fig. 3) and a cut corner on the wire lead lot label (see Fig. 4), this notification does not apply. These markings denote that the lamp has been tested for performance by the manufacturer.
  - If one or more lamps from the affected lots are currently in your inventory and do not comply with the above note, please discard the lamp and please follow the instructions on page 5 to request a replacement.
- If the Halogen Lamp currently installed in your System fails approximately 100 hours after installation, please follow the instructions on page 5 to request a replacement.
- Complete and return the Field Correction Effectiveness Check attached to this letter within 30 days.

Please review this letter with your Medical Director.

Please retain this letter with your laboratory records, and forward this letter to those who may have received a halogen lamp with the lot numbers specified within this document.

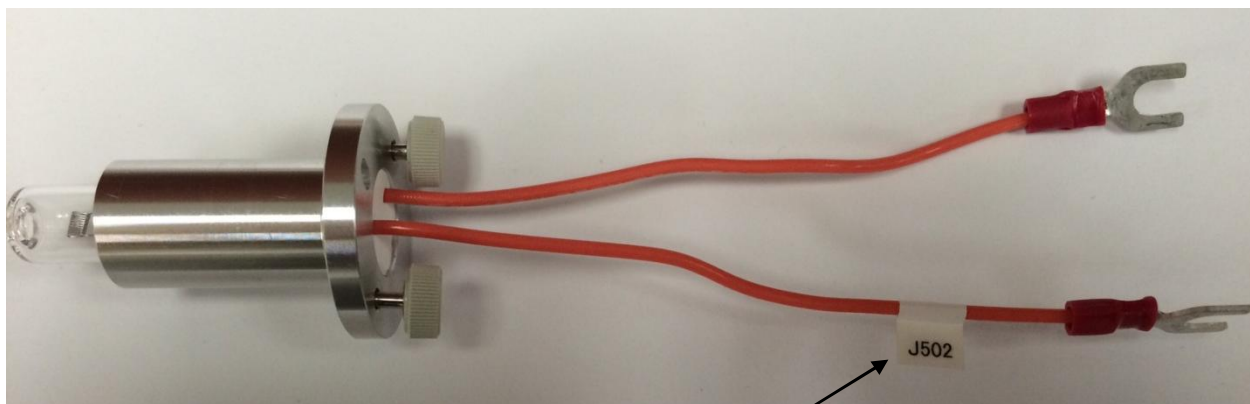
We apologize for the inconvenience this situation may cause. If you have any questions, please contact your Siemens Customer Care Center or your local Siemens technical support representative.

ADVIA is a trademark of Siemens Healthcare Diagnostics.

Figure 1 – Identifying the Halogen Lamp Lot Number on the Lamp Packaging



Figure 2 – Identifying the Halogen Lamp Lot Number on the Lamp's Wire Lead



Lot number identification tag on the  
Lamp's wire Lead.

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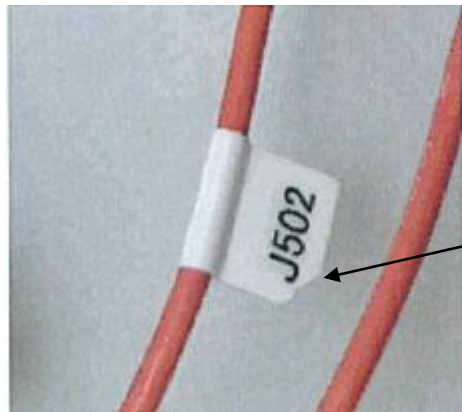
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Figure 3 – Identifying Lamp Packaging Tested by Manufacturer



A green dot on the packaging indicates the lamp was tested by the Manufacturer.

Figure 4 – Identifying Tested Halogen Lamp Lot Number on the Lamp's Wire Lead



Lamps that were tested by the Manufacturer have a corner cut off of the Lot Number Tag on the Lamp's Wire Lead.

## FIELD CORRECTION EFFECTIVENESS CHECK

### Potential for Halogen Lamp Premature Failure

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Customer Notification CHI-16-01.A.OUS dated November, 2015 regarding Potential for Premature Halogen Lamp Failure. Please read each question and indicate the appropriate answer. Fax this completed form to Siemens Healthcare Diagnostics at the fax number provided at the bottom of this page.

1. I have read and understood the Customer Notification instructions provided in this letter. Yes ☐ No ☐
2. Do you now have any of the noted product on hand? Please check inventories before answering. Yes ☐ No ☐

If the answer to the question above is yes, please complete the table below to indicate the quantity of affected product in your laboratory and replacement product required.

| Product Description<br>Product Catalog #/SMN #/Lot #                                   | Quantity of Affected Product in<br>inventory that has been<br>discarded | Replacement Quantity<br>Required |
|--|---|----------------------------------|
| Halogen Lamp – SMN 10309448,<br>Lots J411, J412, J501, J502,<br>J503, J504, J505, J506 |   |                                  |

Name of person completing questionnaire: \_\_\_\_\_

Title: \_\_\_\_\_

Institution: \_\_\_\_\_

Instrument Serial Number: \_\_\_\_\_

Street: \_\_\_\_\_

City: \_\_\_\_\_

State: \_\_\_\_\_

Phone: \_\_\_\_\_

Country: \_\_\_\_\_

Customer Sold To #: \_\_\_\_\_

Customer Ship To #: \_\_\_\_\_

Please fax this completed form to the Customer Care Center at (###) ###-####. If you have any questions, contact your local Siemens technical support representative.

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