**Reagent Batch Failure Notification Form – NCSP Notification**

**Quality Measures for HPV NAT (applies to all testing settings, including screening, test of cure and self-collected specimens)**

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| S5.5 If a reagent batch failure is detected by a laboratory, the laboratory must investigate the cause and take appropriate remedial action  C5.5 If the batch failure relates to a reagent failure with the potential to impact on the quality of testing of other providers, the laboratory must notify the TGA and NCSP immediately so that other users can be notified. |

This template outlines the required information, including the date of reagent batch failure, reagent data (lot numbers and expiry dates) and contact details.

Laboratories **must** notify the NCSP via the Australian Government Department of Health through the [NCSROperations@health.gov.au](mailto:NCSROperations@health.gov.au) inbox.

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| **Name and address of pathology laboratory** |  |
| **Pathology laboratory contact details including responsible Pathologist (phone number and email)** |  |
| **Date of reported reagent batch failure** |  |
| **HPV test type (manufacturer and device)** |  |
| **Reagent batch Lot numbers and expiry date**  *Please list all Lot numbers and expiry dates for any reagents used as part of this batch of tests under the general process categories listed below. Where a reagent is used at multiple steps in the process please repeat under each category.* | |
| 1. Control kit |  |
| 1. Cellular (LBC) extraction kit |  |
| 1. Nucleic acid extraction kit |  |
| 1. Amplification kit |  |
| 1. Detection kit |  |
| 1. Wash buffer |  |