AFFYMETRIX®

Data Sheet

HT Array Replacement Guideline

The integrated Affymetrix® platform is designed to provide our customers with high-quality data and consistent results. We are dedicated to the Affymetrix customer and it is our standard policy to assist the GeneChip® Array Station (GCAS) user when, even in the rarest of cases, an ambiguous result is encountered. This document is intended to clarify situations where Affymetrix HT plate brand array replacement may be appropriate. In addition, we provide an explanation of the steps in the replacement process, as well as guidelines defining the information we need to understand and evaluate a specific replacement request. Our goal is to help expedite your request by resolving GCAS microarray concerns as quickly as possible, allowing you to obtain the industry-standard, high-quality data expected and delivered by Affymetrix HT plate arrays.

In most cases, issues with data quality are resolved by simply adjusting one or more experimental conditions. However, in the event where data are compromised through no fault of the customer, arrays will be considered for replacement on a case-by-case basis.

Definition of Arrays Considered for Replacement

Microarray data quality is determined by the metrics supplied in the report (.rpt) file generated by Affymetrix® software and also by the consistency of the expression data when compared to other data in the data set. For a peg array to be replaced, the variance of the data derived from the peg array in question must be greater than normal variance observed between normal sample replicates, and must be caused by a physical failure in the HT plate, equipment or Affymetrix-supplied reagents. This measurement is often described on expression arrays by the false change calculation of >1 percent or 2 percent Increase, or Decrease calls that are greater than two-fold when examining the same hybridization cocktail on different arrays. However, given that this is not commonly done during the course of an experiment and is not calculated for our genotyping arrays, we will also consider other determinants of variation. These measurements are statistical or quantitative in nature, and can be used to identify data which are outside of the boundaries of normal variation between biological replicates.

When there are questions regarding peg array performance, such as low intensity, an Affymetrix representative will investigate the performance of the hybridization controls and other standard probe sets to determine if the array is functioning properly.

HT Array Replacement Due to Physical Damage

Affymetrix will replace HT arrays which exhibit physical damage that is independent of operator error. These artifacts can include scratches, surface damage, inclusions, shadows or specks that may be found on the synthesized portion of the probe array. These artifacts must be of such a significant dimension that the quality of the data is demonstrably affected (about 10 percent of the surface on an expression HT array). Any physical damage on the HT plate preventing proper processing of the plate will also qualify the array to be replaced.

HT Array Replacement Due to Instrumentation

For customers following standard Affymetrix protocols, HT arrays will be replaced if a GCAS® system under warranty or covered by a valid Affymetrix service contract malfunctions through no fault of the user, and this equipment malfunction causes the HT array(s) to be rendered un-analyzable or data quality is otherwise compromised.

In no case will Affymetrix be responsible to replace HT arrays where the relevant written protocols and standard processes as defined by Affymetrix were not followed or where operator error causes such malfunction.

HT Array Replacement Due to Reagents

Peg arrays will be replaced if, independent of operator error, data from a peg array are compromised by one or more components of an Affymetrix-validated reagent kit. The customer must also follow the standard Affymetrix protocols contained in the GeneChip® Expression Analysis Technical Manual or other Affymetrix-validated protocols. In no case will Affymetrix be responsible for replacement of arrays due to assay failure where the protocols as described in the Affymetrix technical manuals, using Affymetrix-validated reagents, are not followed.

Information Required to Process an HT Array Replacement Request

- The .rpt file for the array in question
- The peg array type and lot number
- A copy of the image if the concern relates to an image anomaly (copy the image in the Affymetrix software and paste into a Word document)
- Other supporting information relevant to the anomaly
- The array should be retained and returned to Affymetrix if requested

Replacement Request Process

1. Prepare an itemized list of the peg array(s) affected along with lot number, report (.rpt) file information derived from the Affymetrix software, and the nature of the anomaly, along with an explanation describing the extent of how the data are compromised. For any physical damage issues, a copy of the peg array's image should also be provided. The customer should keep the HT plate in question accessible in case Affymetrix requests return of the plate to assess the nature of the issue.
2. Contact the appropriate Affymetrix representative within one month of completion of image (.dat) generation regarding the array.
3. The Affymetrix representative may request additional supporting information, such as experiment (.exp) and image (.dat) files, or other information to aid in the replacement assessment.

After receiving all requested information, the decision to replace a peg array will be based on the loss of data integrity. If the results of the investigation determine that data error is a result of the experimental or assay conditions, the HT plate will not be replaced. An Affymetrix representative will notify you of the outcome of the investigation and submit a replacement request, if appropriate.

For standard HT plate arrays, replacements are usually received within 10 business days. Replacements may only be for the same array in which the anomaly was found. Replacements for custom arrays will normally consist of a credit toward the next purchase of that custom array.

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