

7 September 2010

Reference: EPI TF 10014

Corrective and Preventive Action points to consider to address centers exceeding Alert Levels

For any center that exceeds the Alert Levels as defined in the Donor Epidemiology Approach by reporting more confirmed positive donors than allowed, an investigation should be conducted to analyse the data and the operation of the donor center to determine possible causes for exceeding the Alert Levels. The investigation should also evaluate what, if any, corrective actions are indicated. Corrective actions should be proposed to mitigate the higher than allowable number of confirmed positive donors to bring the positivity rates back to acceptable levels and to prevent recurrence.

Scope:

The purpose of this document is to provide a general framework to identify appropriate corrective actions when centers exceed Alert Levels. The individual review process and development of a corrective action plan should be adapted to the individual situation.

Investigations and corresponding actions are most likely found in the following categories:

Review positive serological and NAT virus test results

Look for commonalities among the positive reactions:

1. Donor Demographics
2. Donation characteristics
 - I. Dates of positive donations and previous and subsequent donations
3. Testing characteristics

Based on review of positive results, one or more of the following may be indicated:

1. Donor Recruitment/Retention
 - I. Review Donor screening and exclusion criteria

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2. Donor suitability

- I. Review Donor exclusion criteria
- II. Review risk education process for donors

3. Employees:

- I. Review employee staffing—numbers, education, training, recruitment techniques
- II. Evaluate knowledge and competency of employees with respect to infectious diseases and risk factors
- III. Enhance training program for personnel involved in the Donor screening process

4. Internal Quality and Audit program

- I. Evaluate observations made during recent internal and external audits, corporate performance visits as well as recent Quality Assurance Observations
- II. Consider whether there are areas, such as donor health history determination, screening and acceptance procedures, that need increased focus in future audits
- III. Consider individual center's improvement strategies

5. Review of center's viral marker history

Review of the above functions will determine where there may be identifiable causes for increased viral marker positives. Knowing the root cause enables specific corrective and preventive actions to be developed and implemented.