

## Position Statement

**Subject:** Sample requirements for medical genetic testing:  
Do genetic tests demand a different standard?  
**Approval Date:** November 2007, November 2012  
**Review Date:** November 2014  
**Review By:** Genetics AC  
**Number:** 3/2007

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### 1. Background

The majority of errors in medical testing are not analytical but reflect events that occurred outside the laboratory, including errors in sample collection. In many settings, the collection and identification of samples for medical testing are carried out by personnel who are not employed by or accountable to the testing service. External quality assurance programs may not identify these external events.

#### 1.1 Sample errors may be difficult to identify.

An erroneous test result can often be identified by it being inconsistent with other current or historical information about the patient. In the absence of evidence corroborating a test result, there may be little to suggest to the pathologist or clinician that the wrong sample has been analysed. This is of particular concern in genetic testing of an unaffected person to determine whether they carry a mutation identified in an affected relative. In such testing, there is, by definition, no other evidence to corroborate the result of the genetic test.

#### 1.2 Sample errors may be irrelevant or carry major clinical consequences.

If the prior probability of a two unrelated patients having a mutation in a specific gene is low, then a sample swap may still yield the correct result i.e. normal, on this basis alone. However, the probability of a sample error being clinically significant rises as the prior probability of an abnormal result increases. This is relevant in genetic testing of relatives for a Mendelian disorder.

#### 1.3 Sample errors carry implications that extend beyond the immediate care of the patient.

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**DJ Losen**



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