

**Patient information (if applicable)**

MRN:

DOB:

Loc:

Name:

Specimen Number(s):

**Product information (if applicable)**

Unique ID:

Exp:

Product:

**Briefly explain the nature of the situation and reason for the variance**

**List individuals notified (include name/title/date/time)**

**Evaluation**

Comments

FDA Reportable?

Final Medical Director Review:

Date: