

## **Questions for Ballot Vote**

March 26, 2014  
Molecular and Clinical Genetics Panel

P130001  
Epi proColon®  
Epigenomics AG

The following questions relate to the approvability of Epi proColon.

### **Question 1**

Is there reasonable assurance that Epi proColon is safe for use in patients who meet the criteria specified in the proposed intended use?

### **Question 2**

Is there reasonable assurance that Epi proColon is effective for use in patients who meet the criteria specified in the proposed intended use?

### **Question 3**

In patients who meet the criteria specified in the proposed intended use, do the benefits outweigh the risks for use of Epi proColon?