



Annex 1

Statutory fees for testing of samples

<i>Column 1</i> <i>Product type</i>	<i>Column 2</i> <i>Fee payable where the licensing authority carries out a full assessment</i>	<i>Column 3</i> <i>Fee payable where the licensing authority carries out a paper-based assessment</i>
1. Plasma Pools which require—		
(a) three or fewer tests	£180	£90
(a) four or five tests	£215	£90
(a) six or more tests	£230	£90
2. Band A	£1,660	£305
3. Band B	£1,910	£305
4. Band C	£2,340	£305
5. Band D	£3,690	£677
6. Band E	£6,410	£677
7. Band F	£10,350	£677

(5) In this paragraph—

“Band A” means a single component product, other than Botulinum toxin, requiring five or fewer in vitro tests;

“Band B” means Factor VIII, Factor IX or intravenous immunoglobulin;

“Band C” means a multi-component product, or Botulinum toxin, requiring five or fewer in vitro tests;

“Band D” means a product requiring six to nine in vitro tests;

“Band E” means a product requiring—

- (a) ten or more in vitro tests, or
- (b) one or more in vivo tests;

“Band F” means a product—

- (a) which requires one or more tests that must be carried out under containment measures applicable to hazard Group 3 or 4 biological agents under the Control of Substances Hazardous to Health Regulations 2002; or
- (b) requires the use of human cells or tissues as part of its testing;

“Single component product” means a product containing a single analyte that requires testing;

“Multi-component product” means a product containing two or more analytes that require testing.