

# IQ / OQ / PQ

Laboratory Instrument Validation  
Performed and Documented in GLP Format

## CE Systems

Biomatic Technologies

### OQ — Operational Qualification

#### CE Systems

- Temperature accuracy and stability of capillary compartment
- Holmium Oxide wavelength scan (if applicable)
- Detector lamp intensity, and wavelength accuracy
- Detector noise and drift
- Injection precision

Five repeated injections of standard Imidazole, Metmorfin, and Histidine sample (using Hydrostatic and electrokinetic injections)  
Compare area count and retention time deviations

- Injection linearity

1, 2, 3, and 4 second injections of standard Imidazole, Metmorfin, and Histidine sample (using Hydrostatic and electrokinetic injections).  
Compare linearity of area counts

- Detector linearity

Five injections of increasing concentration standard Imidazole, Metmorfin, and Histidine samples (using hydrostatic injection).  
Compare linearity of area counts

- High voltage accuracy and stability

### IQ — Installation Qualification

- Inventory of instruction manuals, components and serial numbers
- Installation verification

### PQ — Performance Qualification

- System performance and robustness

Typically an injection of a low-concentration sample, repeated five times  
Compare area count and retention time deviations

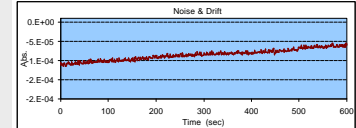
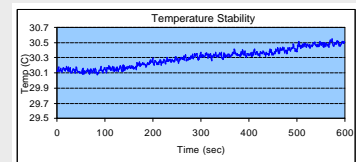
- Data analysis verification

Biomatic Technologies Specialties

- Reconditioned Lab Equipment
  - Service & Maintenance of Lab Equipment
    - Instrument IQ, OQ, PQ Validation
    - Asset Management & Inventory Control
    - Contract R & D and Consulting

Biomatic Technologies Inc.  
124 Grove St., Suite 225  
Franklin, MA 02038  
Phone: (877) 741-3600  
(Toll Free)  
(508) 541-3600  
FAX: (508) 541-2323  
[www.biomatic.com](http://www.biomatic.com)

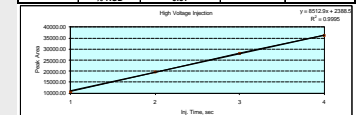
### Data Analysis of Test Results Graphical Display & Charts



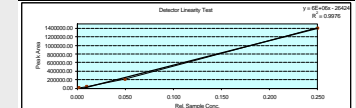
Set Temperature	30 C	Noise	2.13E-05 AU
Observed	30.30	Drift	5.97E-05 AU/Hour
%RSD	0.12		

Vacuum Injection Repeatability Test - ABI 270A CE			
2 Sec. 5 Hg-inch Injections - Metmorfin Peak (#2)			
File Name	Run #	Migration Time, min	Area
bin.6	1	3.41	311182.00
bin.7	2	3.51	294892.00
bin.8	3	3.49	289772.00
bin.9	4	3.49	300895.00
bin.10	5	3.49	295348.00
Average		3.50	298357.80
Std Dev.		0.01	8178.94
%RSD		0.31	2.74

High Voltage Injection Linearity Test - ABI 270A CE				
High Voltage Injection, 5KV - Imidazole Peak (#1)				
File Name	Inj. Time, sec	Migration Time, min	Area	Height
bin.37	1	3.13	10704.00	47.88
bin.38	2	3.12	19595.00	92.65
bin.39	3	3.10	28158.00	167.64
bin.40	4	3.10	35226.00	184.23
Average		3.11	35226.00	184.23
%RSD		0.37		



Detector Linearity Test - ABI 270A CE			
2 Sec. Vacuum Injection, 5 Hg-inch - Imidazole Peak (#1)			
File Name	Rel. Sample Conc. mg/ml	Migration Time, min	Area
bin.26	0.002	3.07	11689.00
bin.16	0.01	2.98	42522.00
bin.17	0.05	2.98	210882.00
bin.21	0.25	3.05	1468017.00
Average		3.02	
%RSD		1.67	



Performance Qualification - ABI 270A CE System						
Vacuum Injection Repeatability Test						
File Name	Run #	Migration Time, min	Area	Height	Average	%RSD
bin.6	1	3.41	311182.00	47.88		
bin.7	2	3.51	294892.00	92.65		
bin.8	3	3.49	289772.00	167.64		
bin.9	4	3.49	300895.00	184.23		
bin.10	5	3.49	295348.00			
Average		3.50	298357.80			
Std Dev.		0.01	8178.94			
%RSD		0.31	2.74			