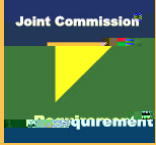




# Prepublication Requirements

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## New and Revised Laboratory Requirements Related to Histocompatibility

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D`YUgY`bchY.Ä Y @^!^Äæ] ] |ä&æà|^ÉÄc@i•Ä!^] [ !cÄ•@ [ , •Ä& ~ !!^] cÄ•cæ} äæ!ä•Äæ} äÄÖÜ•Ä-ä!•cÉÄ , äc@Ää^|^c^äÄ|æ} \* ~æ\*^Ä•c!~&\É c@! [ ~\*@ÉÄV@^] ÉÄc@^Ä!^çj•^âÄ!^~ ä!^ { ^} cÄ- [|| [ , •Ää} Äà [ |äÄc^çcÉÄ , äc@Ä} ^ , Ä|æ} \* ~æ\*^Ä ~ } ä^!|ä} ^äÉ



Leadership (LD) Chapter

**LD.04.05.01**

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**Element(s) of Performance for LD.04.05.01**

BYk`9D`' H\Y`UVcfUhcfm`X]fYWhcf`]g`cbg]hY`Uh`h\Y`UVcfUhcfm`Uh`YUgh`cbWY`Y jYfm`g]I`a`cbh`gž`k]h`Uh`YUgh`Zc`i`f`a`cbh`g`VYh`k`YYb`h`Y`a`]b]a`i`a`h`k`c`cbg]h`Y`j]g]hg`  
 BchY`%`H\Y`UVcfUhcfm`X]fYWhcf`]g`UWWYgg]V`Y`hc`h\Y`UVcfUhcfm`hc`dfc`j]XY`cbg]hYž`h`Y`d`cbYž`cf`Y`YWhfcb]W`Wcbg`i`hUh]cb`Ug`b`Y`WYggUfm`  
 BchY`&`H\Y`cbg]h`Y`j]g]hg`UfY`XcW`i`a`YbhYX`UbX`]bW`i`XY`Y`j]XYbWY`cZ`dYfZcf`a`]b`[`UWh]j]h]Yg`h`Uh`UfY`dUfh`cZ`h`Y`UVcfUhcfm`X]fYWhcf]g`fYgdcbg]V`]h]Yg`  
 BchY`'`H\Y`UVcfUhcfm`X]fYWhcf`a`U`\_Yg`WYfhU]b`h`Uh`U`[`YbYfU`g`i`dYf`j]gcf`dfc`j]XYg`cb!g]h`Y`g`i`dYf`j]g]cb`cZ`][`W`c`a`d`Y`I]hm`h`Ygh`dYfZcf`a`UbWY`Vm`h`Ygh]b`[`dYfgcbbY`e`i`U`]YX`i`bXYf`  
 (&`7`:`F`(-`'`%`(`,`-`flV`l`l)l`"

Ⓓ 8cW i a YbhUh]cb`]g`fYe i ]fYX

BYk`9D`%\$ H\Y`DDA`UVcfUhcfm`X]fYWhcf`]g`fYgdcbg]V`Y`Zcf`h`Y`Zc`c`k]b[`  
 !`9`j`U`i`Uh]b[`h`Y`Wc`a`dYhYbWm`cZ`U`h`Ygh]b[`dYfgcbbY`hc`Ybg`i`fY`h`Uh`h`Y`gh`UZZ`a`U]bhU]bg`h`Y]f`Wc`a`dYhYbWm`hc`dYfZcf`a`h`Ygh`dfc`WYX`i`fYg`UbX`fYdcfh`h`Yghg`dfc`a`dh`mž`UWW`i`fUhY`mž`UbX`dfcZ]W]Ybh`m`  
 !`9`j`U`i`Uh]b[`UbX`XcW`i`a`Ybh]b[`h`Y`dYfZcf`a`UbWY`cZ`]bX]j]X`i`U`g`fYgdcbg]V`Y`Zcf`DDA`h`Ygh]b[`Uh`YUgh`gY`a`Ubb`i`U`m`X`i`f]b[`h`Y`Z]fgh`m`YUf`h`Y`]bX]j]X`i`U`h`Yghg`dUh]Ybh`gdYW`a`Ybg`H`Y`f`Y`U`Z`h`Y`fž`Y`j`U`i`Uh]cbg`UbX`XcW`i`a`YbhUh]cb`a`i`gh`VY`dYfZcf`a`YX`Uh`YUgh`Ubb`i`U`m`  
 BchY`H\Y`dfc`WYX`i`fYg`Zcf`Y`j`U`i`Uh]cb`cZ`h`Y`Wc`a`dYhYbWm`]bW`i`XY`V`i`h`UfY`bch`]a`]h`YX`hc`h`Y`Zc`c`k]b[`  
 !`8]fYWh`c`VgYf`j`Uh]cbg`cZ`fc`i`h]bY`dUh]Ybh`h`Ygh`dYfZcf`a`UbWYž`]bW`i`X]b[`ž`]Z`Udd`]WUV`Yž`gdYW]a`Yb`UbX`]b[`ž`dfc`WYgg]b[`ž`UbX`h`Ygh]b[`  
 !`Ac]b]hcf]b[`h`Y`fYWcfX]b[`UbX`fYdcfh]b[`cZ`h`Ygh`fYg`i`hg`



Quality System Assessment for Nonwaived Testing (QSA) Chapter

**QSA 1201.01**

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**Element(s) of Performance for QSA 1201.01**

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FYj]gYX'9D'\* -Z'h\Y''UVcfUhcfm' i gYg]a a i bc`c [JW'fYU [Ybhg'hc'ZUW]'hUhY'cf'Yb\UbWY'h\Y']gc`Uh]cb'cZ'  
`m a d\cWmhYgž'cf`m a d\cWmhY'g i VgYhgž'h\Y''UVcfUhcfm' a cb]hcf'g'h\Y'YZZ]WUWm'cZ'h\Y' a Yh\cXg'k]h\  
e i U]hm'Wcbhfc`dfcWYX i fYg"

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FYj]gYX'9D', H\Y''UVcfUhcfm' i gYg'U'Wcbh]b i c i g' a cb]hcf]b [ 'UbX'U'Yfh'gmghY a 'hc' a cb]hcf'h\Y'ghcfU [Y  
hY a dYfUh i fY'cZ'gdYW] a Ybg'fiXcbcf'UbX'fYW]d]Ybhl'UbX'fYU [Ybhg" H\Y'gmghY a 'bch]Z]Yg''UVcfUhcfm  
ghUZ' k \Yb'hY a dYfUh i fY''] a ]hg'UfY'YI WYXYX"

UHDJPSSRQ RI



\*Current OSA.12.02.01 through OSA.12.07.01 were deleted and replaced with the following\*

### OSA.12.02.01

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#### Element(s) of Performance for OSA.12.02.01

BYk`9D`% H\Y`UVcfUhcfm`i gYg` \ i a Ub`Y i \_cWmhY`Ubh] [ Yb`fl<@5k`hYf a ]bc`c [ m`h\Uh`WcbZcf a g`hc`h\Y`Kcf`X`  
<YU`h`Cf [ Ub]nUh]cb`fiK <Cl`Bc a YbW`Uh i fY`7c a a ]hhYY`Zcf` :UWhcfg`cZ`h\Y`<@5`GmghY a "

BYk`9D`& H\Y`UVcfUhcfm`XYjY`cdg`UbX`] a d`Y a Ybhg`k f]hhYb`Wf]hYf]U`Zcf`XYhYf a ]b]b [ `k \Yb`Ubh] [ Yb`UbX`  
U`Y`Y`hmd]b [ `Uf`fYe i ]fYX"

Ⓓ 8cW i a YbhUh]cb`]g`fYe i ]fYX

### OSA.12.03.01

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#### Element(s) of Performance for OSA.12.03.01

BYk`9D`% H\Y`UVcfUhcfm` a U\_Yg`U`fYUgcbUV`Y`YZZcfh`hc` \UjY`UjU]UV`Y` a cbh` \m`gYf i a `gdYW] a Ybg`Zcf`U`  
dchYbh]U` `hfUb]gd`Ubh`fYW]d]Ybhg`Zcf`dYf]cX]W`Ubh]VcXm`gWfYYb]b [ ž`]XYbh]Z]WUh]cbz`UbX`Wfcgg a UhW` "

Ⓓ 8cW i a YbhUh]cb`]g`fYe i ]fYX

### OSA.12.04.01

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#### Element(s) of Performance for OSA.12.04.01





**Element(s) of Performance for QSA.12.06.01**

BYk'9D% H\Y`UVcfUhcfm'XcWi a Ybhg'U`'Wcbhfc`'dfcWYX i fYg'dYfZcf a YX'fY`UhYX'hc` \]ghcWc a dUh]V`]hm  
hYgh]b["

- Ⓓ 8cWi a YbhUh]cb`]g'fYe i]fYX

**QSA.13.07.01**

V@^Á|æà [ !æc [ !^Á!^cæá } •Á@ã•c [ [ !\*ã&æ]Á• ] ^&ã { ^ } •Á~ [ !Á ] æcá^ } cÁ&æ!^Á ] ~ ! ] [ •^•É

**Element(s) of Performance for QSA.13.07.01**

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