=gg i YX CWhcVYf &%, &$&(

New and Revised Laboratory Requirements Related to Histocompatibility

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D`YUgY bchY.ÅY@^¦^Åæ]]|â&æà|^ÊÅc@â•Å¦^][¦cÅ•@[¸•Å&˘¦¦^}cÅ•cæ}åæ¦â•Åæ}åÅÒÚ•Å-â¦•cÊÅ¸âc@Åâ^|^c^åÅ|æ}*˘æ*^Å•c¦˘&\Ë c@¦[˘*@ËÅV@^}ÊÅc@^Å¦^çâ•^åÅ¦^˘˘â¦^{^}c•Å~[||[¸Åâ}Åà[|åÅc^¢cËÅ¸âc@Å}^¸Å|æ}*˘æ*^Å˘}å^¦|â}^åÈ

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]hYU h h\Y `UVcfUhcfm Uh `YUgh cbWY YjYfm g]I a cbh\g, k]h\ Uh `YUgh Zc i f a cbh\g VYhkYYb h\Y a]b]a i a hkc cbg]hY j]g]hg.

BchY %. H\Y `UVcfUhcfm X]fYWhcf ]g UWWYgg]V`Y hc h\Y `UVcfUhcfm hc dfcj]XY cbg]hY, hY`Yd\cbY, cf Y`YWhfcb]W Wcbgi`hUh]cb Ug bYWYggUfm.

BchY &. H\Y cbg]hY j]g]hg UfY XcWi a YbhYX UbX]bW`iXY Yj]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` gidYfj]gcf dfcj]XYg cb-g]hY g idYfj]g]cb cZ \][\ Wc a d`YI]hm hYgh dYfZcf a UbWY Vm hYgh]b[ dYfgcbbY` e i U`]Z]YX i bXYf (& 7 : F (- '.%(, -(V)()).

Ⓓ 8cWi a YbhUh]cb]g fYei]fYX

BYk 9D %$ H\Y DDA `UVcfUhcfm X]fYWhcf ]g fYgdcbg]V`Y Zcf h\Y Zc``ck]b[.

- 9jU`iUh]b[h\Y Wc a d\YhbWm cZ U`` hYgh]b[dYfgcbbY` hc YbgifY h\Uh h\Y ghUZZ a U]bhU]bg h\Y]f Wc a dYhbWY hc dYfZcf a hYgh dfcWYifYg UbX fYdcfh hYghg dfc a dh`m, UWWifUhY`m, UbX dfcZ]W]Ybh`m.

- 9jU`iUh]b[ UbX XcWi a Ybh]b[ h\Y dYfZcf a UbWY cZ ]bX]j]XiU`g fYgdcbg]V`Y Zcf DDA hYgh]b[ Uh `YUgh g]m]bbiU``m Xif]b[ h\Y Z]fgt mYUf h\Y ]bX]j]XiU` hYghg dUh]Ybt gdYW] a Ybg. H\YfYUZhYf, YjU`iUh]cbg UbX XcWi a YbhUh]cb a igh VY dYfZcf a YX Uh `YUgh UbbiU``m.

BchY. H\Y dfcWYifYg Zcf YjU`iUh]cb cZ h\Y Wc a dYhbWm ]bW`iXY Vih UfY bch `] a]hYX hc h\Y Zc``ck]b[.

- 8]fYWh cVgYfjUh]cbg cZ fci h]bY dUh]Ybt hYgh dYfZcf a UbWY,]bW`iX]b[, ]Z Udd`]WUV`Y, gdYW] a Yb \UbX`]b[, dfcWYgg]b[, UbX hYgh]b[

- Acb]hcf]b[h\Y fYWcfX]b[UbX fYdcfh]b[cZ hYgh fYgi `hg

Quality System Assessment for Nonwaived Testing (QSA) Chapter

QSA.12.01.01

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Element(s) of Performance for QSA.12.01.01

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FYj]gYX 9D * =Z h\Y `UVcfUhcfm igYg ]a a ibc`c[]W fYU[Ybhg hc ZUW]`]hUhY cf Yb\UbWY h\Y ]gc`Uh]cb cZ `mad\cWmhYg, cf `mad\cWmhY giVgYhg, h\Y `UVcfUhcfm acb]hcfg h\Y YZZ]WUWm cZ h\Y aYh\cXg k]h\ eiU`]hm Wcbhfc` dfcWYXifYg.

ÒÚÁÌ V@^Á|æà[¦æc[¦ˆÁ@æ•ÁæÁ•ˆ•c^{Áâ}Á]|æ&^Á-[¦Á]¦[]^¦Á•c[¦æ*^Áæ}åÁ{æâ}c^}æ}&^Á-[¦à[c@Á¦^&â]â^}c•Ác•Á•^¦æÁæ}åÁ¦^æ*^}c•Áæ&Áæ}]cæà|^Ác^{]^¦æcˇ¦^Á|æ}*^Á-[¦•Á•^¦æÁãå&[{]|[}^}c•ÊÁ&|ˇâå}*ÁæÁc^{]^¦æcˇ¦^Á|æ¦{Á•ˆ•c^{ÁåÁæ}ÁÁ^{¦*^}&^Á|æ]Á-[¦Áæ|c^¦}}æcâç^Á•c[¦æ*^È

FYj]gYX 9D , H\Y `UVcfUhcfm igYg U Wcbh]bicig acb]hcf]b[ UbX U`Yfh gmghYa hc acb]hcf h\Y ghcfU[Y hYadYfUhifY cZ gdYW]aYbg (Xcbcf UbX fYW]d]Ybh) UbX fYU[Ybhg. H\Y gmghYa bch]Z]Yg `UVcfUhcfm ghUZZ k\Yb hYadYfUhifY `]a]hg UfY YlWYYXYX.

U H D J P S S R Q R I

Current QSA.12.02.01 through QSA.12.07.01 were deleted and replaced with the following

QSA.12.02.01

V@^Á|æà[¦æc[¦ˆÁ]^¦~[¦{•Á@˘{æ}Á|^˘\[&ˆc^Áæ}cã*^}ÁÇPŠŒDÁc^]â}*È

Element(s) of Performance for QSA.12.02.01

BYk 9D % H\Y `UVcfUhcfm igYg \imUb `Yi_cWmhY Ubh][Yb (<@5) hYfa]bc`c[mh\Uh WcbZcfag hc h\Y Kcf`X <YU`h\ Cf[Ub]nUh]cb (K<C) BcaYbW`UhifY 7caa]hhYY Zcf :UWhcfg cZ h\Y <@5 GmghYa.

BYk 9D & H\Y `UVcfUhcfm XYjY`cdg UbX]ad`YaYbhg k f]hhYb Wf]hYf]U Zcf XYhYfa]b]b[k\Yb Ubh][Yb UbX U``Y`Y hmp]b[UfY fYei]fYX.

Ⓓ 8cWiaYbhUh]cb]g fYei]fYX

QSA.12.03.01

V@^Á|æà[¦æc[¦ˆÁ]^¦~[¦{•Á@˘{æ}Á|^˘\[&ˆc^Áæ}cã*^}ÁÇPŠŒDÁ•^¦[|[*â&Áæ}cãà[âˆÁ•&¦^^}â}*Áæ}âÁâã^}cã~â&æcã[}È

Element(s) of Performance for QSA.12.03.01

BYk 9D % H\Y `UVcfUhcfm aU_Yg U fYUgcbUV`Y YZZcfh hc \UjY UjU]`UV`Y acbh\`m gYfia gdYW]aYbg Zcf U`` dchYbh]U` hfUbgp`Ubh fYW]d]Ybhg Zcf dYf]cX]W Ubh]VcXm gWfYYb]b[,]XYbh]Z]WUh]cb, UbX Wfcgg aUhW\.

Ⓓ 8cWiaYbhUh]cb]g fYei]fYX

QSA.12.04.01

V@^Á|æà[¦æc[¦ˆÁ&¦[••{æc&@^•Á][c^}cãæ|Á¦^&â]â^}c•Áæ}âÁâ[}[¦Á•Áà^~[¦Á^¦~[¦{^åÈ

Element(s) of Performance for QSA.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[.

(D)   8cWi a YbhUh]cb]g fYei]fYX

QSA.13.07.01

V@^Á|æà[¦æc[¦^Á¦^cæå}•Á@å•c[|[*å&æ|Á•]^&å{^}•Å~[¦Á]æcå^}cÅ&æ¦^Á]˘¦][•^•È

Element(s) of Performance for QSA.13.07.01

ÒÚÁG   Tå&¦[•&[]å&Á•|åå^•ÊÁ]æ¦æ~å}Áà|[&\•ÊÁà[}^Á{æ¦¦[¸Áæ•]å¦æc^•ÊÁ^^å|^Áàå]]•^Á•]^&å{^}•ÊÁæ}åÁ*¦[••Á
cå••˘^Á•]^&å{^}•Áæ¦^¦¦^cæå}^åÁã}Áæ&&[¦åæ}&^Á¸åc@Á|æ¸Áæ}åÁ¦^*˘|æcå[}Áæ}åÁæ•Áå^-å}^åÁà^Á[¦*æ}å:æcå[}Á
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