

## Nivel 1

### Hemoglobina A1c

#### I. Información general

##### Sistema de medición

Variant II Turbo

**ETmp%**

5.000

##### Lote de reactivos

B1: 64390672 BB: 990283 WS: 64381395

**Numero de datos N**

25

##### Lote de calibrador

S00346

**Sigma R**

1.200

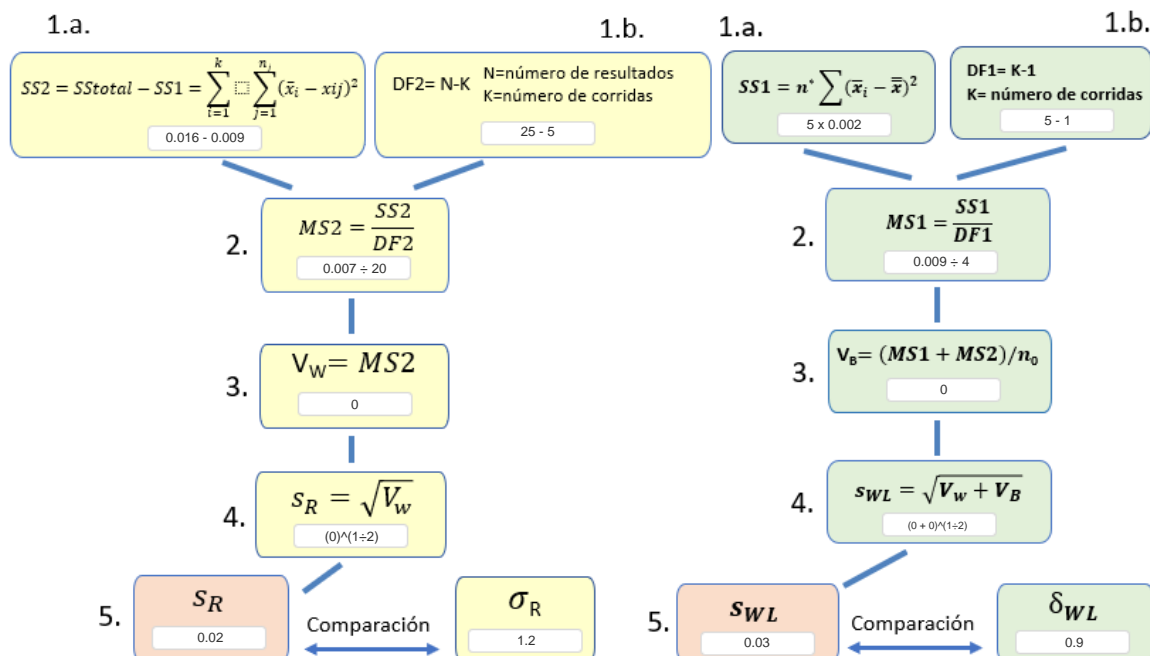
##### Material utilizado

740 Lyphochek Diabetes Control

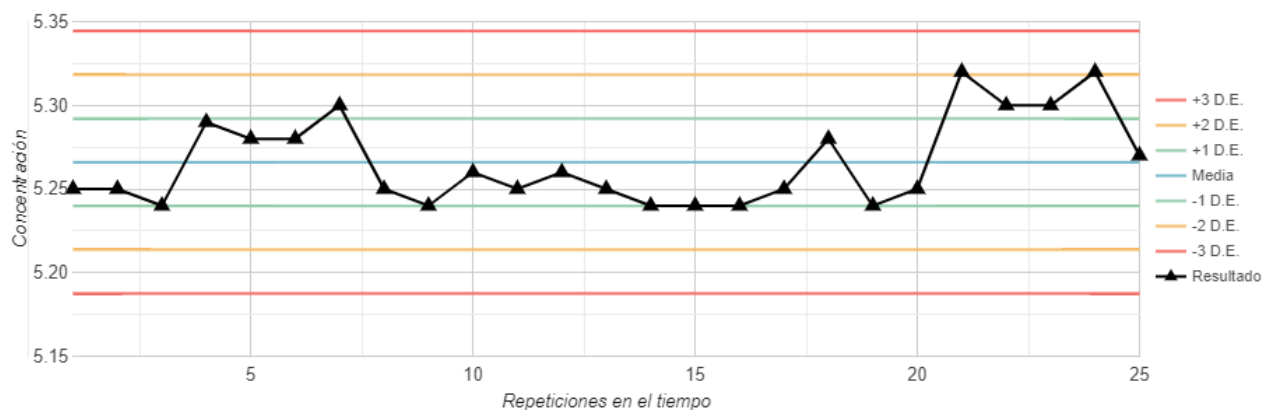
**Sigma WL**

0.900

#### II. Diagrama de flujo SR y SWL



#### III. Gráfica de control



**IV. Recolección de información**

Corrida	Fecha	R1	R2	R3	R4	R5	Promedio	D.E.
C1	2021-05-10 12:28:47	5.250	5.250	5.240	5.290	5.280	5.26	0.02
C2	2021-05-10 12:28:47	5.280	5.300	5.250	5.240	5.260	5.27	0.02
C3	2021-05-10 12:28:47	5.250	5.260	5.250	5.240	5.240	5.25	0.01
C4	2021-05-10 12:28:47	5.240	5.250	5.280	5.240	5.250	5.25	0.02
C5	2021-05-10 12:28:47	5.320	5.300	5.300	5.320	5.270	5.3	0.02
Gran media: 5.27					D.E.: 0.03			

**V. Verificación de la precisión**

Fórmula	C1	C2	C3	C4	C5
$(\bar{X}_i - \bar{\bar{X}})$	-0	0	-0.02	-0.01	0.04
$(\bar{X}_i - \bar{\bar{X}})^2$	0	0	0	0	0

Diferencia de las medias al cuadrado					
Corrida	R1	R2	R3	R4	R5
C1	0	0	0	0	0
C2	0	0	0	0	0
C3	0	0	0	0	0
C4	0	0	0	0	0
C5	0	0	0	0	0

SS1	
$n \sum_{i=1}^k (\bar{X}_i - \bar{\bar{X}})^2$	0.01

SS2	
$\sum_{i=1}^k \sum_{j=1}^{n_j} (\bar{X}_i - x_{ij})^2$	0.01

$DF1 = k - 1$	$DF2 = N - k$	$MS1 = SS1 / DF1$	$MS2 = SS2 / DF2 = V_w$	$n_0$	$V_B = (MS1 - MS2) / n_0$
4	20	0	0	5	0

$s_R = \sqrt{V_w}$	0.02	$s_{wL} = \sqrt{V_w + V_B}$	0.03
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**VI. Estimación del sesgo**

INSERTO							
Media	5.200	D.E.	0.200	U	0.260	k	1.960
$se_{\bar{x}} = \sqrt{\frac{1}{nRun} \left[ s_{WL}^2 - \left( \frac{nRep-1}{nRep} \right) s_R^2 \right]}$		$se_{RM} = \frac{U}{k}$		$se_C = \sqrt{se_{\bar{x}}^2 + se_{RM}^2}$			
0.01		0.13		0.13			
$df_{\bar{x}} = nRun - 1$		$df_C = df_{\bar{x}} \cdot (se_C / se_{\bar{x}})^4$		$m = t_{1-\alpha/2, nSam, v}$			
4		149158.44		1.96			
Verification Interval = TV ± (m • se <sub>C</sub> )						4.94 - 5.46	
Sesgo de la prueba %		1.27 %		Sesgo de la prueba en unidades		0.07	

GRUPO PAR							
Media	5.280	D.E.	1.900	Nlab	74		
$se_{\bar{x}} = \sqrt{\frac{1}{nRun} \left[ s_{WL}^2 - \left( \frac{nRep-1}{nRep} \right) s_R^2 \right]}$		$se_{RM} = \frac{s_{RM}}{\sqrt{nLab}}$		$se_C = \sqrt{se_{\bar{x}}^2 + se_{RM}^2}$			
0.01		0.22		0.22			
$tau = \frac{se_{RM}}{se_{\bar{x}}}$		$df_C$		$m = t_{1-\alpha/2, nSam, v}$			
23.08		49		20.09			
Verification Interval = TV ± (m • se <sub>C</sub> )						0.84 - 9.72	
Sesgo de la prueba %		-0.27 %		Sesgo de la prueba en unidades		-0.01	

## Nivel 2

### Hemoglobina A1c

#### I. Información general

##### Sistema de medición

Variant II Turbo

ETmp%

5.000

##### Lote de reactivos

B1: 64390672 BB: 990283 WS: 64381395

Numero de datos N

25

##### Lote de calibrador

S00346

Sigma R

0.800

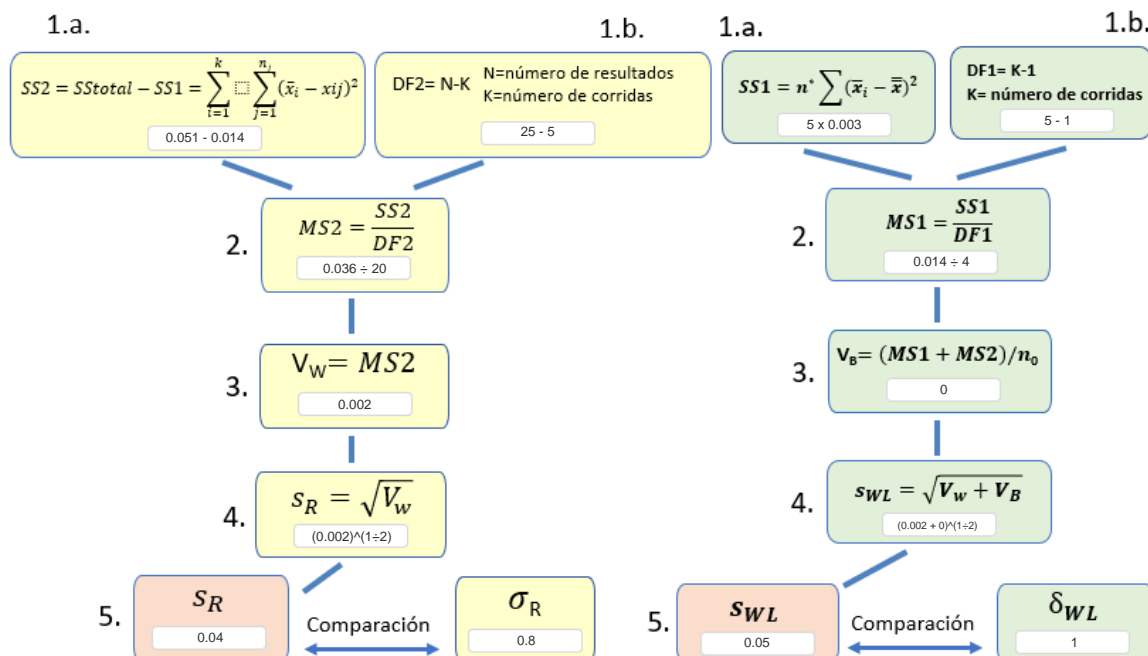
##### Material utilizado

740 Lyphochek Diabetes Control

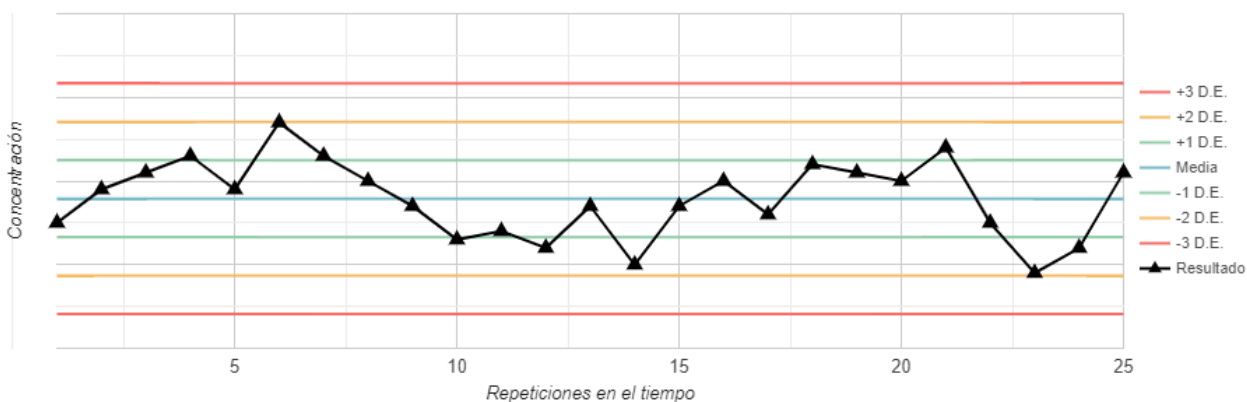
Sigma WL

1.000

#### II. Diagrama de flujo SR y SWL



#### III. Gráfica de control



**IV. Recolección de información**

Corrida	Fecha	R1	R2	R3	R4	R5	Promedio	D.E.
C1	2021-05-10 12:28:47	9.950	9.990	10.010	10.030	9.990	9.99	0.03
C2	2021-05-10 12:28:47	10.070	10.030	10.000	9.970	9.930	10	0.05
C3	2021-05-10 12:28:47	9.940	9.920	9.970	9.900	9.970	9.94	0.03
C4	2021-05-10 12:28:47	10.000	9.960	10.020	10.010	10.000	10	0.02
C5	2021-05-10 12:28:47	10.040	9.950	9.890	9.920	10.010	9.96	0.06
Gran media: 9.98						D.E.: 0.05		

**V. Verificación de la precisión**

Fórmula	C1	C2	C3	C4	C5
$(\bar{X}_i - \bar{\bar{X}})$	0.02	0.02	-0.04	0.02	-0.02
$(\bar{X}_i - \bar{\bar{X}})^2$	0	0	0	0	0

SS1	
$n \sum_{i=1}^k (\bar{X}_i - \bar{\bar{X}})^2$	0.01

**Diferencia de las medias al cuadrado**

Corrida	R1	R2	R3	R4	R5
C1	0	0	0	0	0
C2	0	0	0	0	0
C3	0	0	0	0	0
C4	0	0	0	0	0
C5	0.01	0	0.01	0	0

SS2	
$\sum_{i=1}^k \sum_{j=1}^{n_j} (\bar{X}_i - x_{ij})^2$	0.04

$DF1 = k - 1$	$DF2 = N - k$	$MSI = SS1 / DF1$	$MS2 = SS2 / DF2 = V_W$	$n_0$	$V_B = (MSI - MS2) / n_0$
4	20	0	0	5	0

$$s_R = \sqrt{V_W} \quad \mathbf{0.04} \quad s_{WL} = \sqrt{V_W + V_B} \quad \mathbf{0.05}$$

**VI. Estimación del sesgo**

**INSERTO**

Media **9.800** D.E. **0.370** U **0.490** k **1.960**

$$se_{\bar{x}} = \sqrt{\frac{1}{nRun} \left[ s_{WL}^2 - \left( \frac{nRep-1}{nRep} \right) s_R^2 \right]} \quad \mathbf{0.01}$$

$$se_{RM} = \frac{U}{k} \quad \mathbf{0.25}$$

$$se_C = \sqrt{se_{\bar{x}}^2 + se_{RM}^2} \quad \mathbf{0.25}$$

$$df_{\bar{x}} = nRun - 1$$

**4**

$$df_C = df_{\bar{x}} \cdot (se_C / se_{\bar{x}})^4$$

**780174.15**

$$m = t_{1-\alpha/2, nSam, v}$$

**1.96**

$$\text{Verification Interval} = TV \pm (m \cdot se_C)$$

**9.31 - 10.29**

Sesgo de la prueba %

**1.82 %**

Sesgo de la prueba en unidades

**0.18**

**GRUPO PAR**

Media **9.930** D.E. **2.900** Nlab **75**

$$se_{\bar{x}} = \sqrt{\frac{1}{nRun} \left[ s_{WL}^2 - \left( \frac{nRep-1}{nRep} \right) s_R^2 \right]} \quad \mathbf{0.01}$$

$$se_{RM} = \frac{s_{RM}}{\sqrt{nLab}} \quad \mathbf{0.33}$$

$$se_C = \sqrt{se_{\bar{x}}^2 + se_{RM}^2} \quad \mathbf{0.34}$$

$$tau = \frac{se_{RM}}{se_{\bar{x}}}$$

**28.12**

$$df_C$$

**49**

$$m = t_{1-\alpha/2, nSam, v}$$

**20.09**

$$\text{Verification Interval} = TV \pm (m \cdot se_C)$$

**3.2 - 16.66**

Sesgo de la prueba %

**0.49 %**

Sesgo de la prueba en unidades

**0.05**