Clinical evaluation report of BeneCheck Multi-Monitoring System cholesterol strips

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Clinical evaluation report of BeneCheck Multi-Monitoring System cholesterol strips TMU-JIRB No.: 201311010	
report number	BKP-CS-2014-13
Set the date	2014.10. 31
	1

Experience the implementation of the unit	Laboratory diagnosis of medical examiner
Test execution site	Wanfang Hospital Laboratory Diagnosis
the host	Wang Jiongzhong

1. Purpose

   The purpose of this clinical performance evaluation was to demonstrate that using BeneCheck Multi-Monitoring System and cholesterol strips were able to obtain valid cholesterol results. Comparison of fresh finger capillary blood and forearm venous blood using the Beckman Coulter analyzer was as reference.

2. Experimental equipment and materials

   2.1 Equipment

      2.1.1 Beckman Coulter Analyze

      2.1.2 BeneCheck Multi-Monitoring System

      2.1.3 EasyTouch meter (Biptik Inc.)

      2.1.4 Accutrend GCT meter (Roche)

   2.2 Materials

      2.2.1 Beckman Coulter reagents

      2.2.2 BeneCheck cholesterol strips two lots
         4662, 4592.

      2.2.3 EasyTouch cholesterol strips

      2.2.4 Accutrend GCT cholesterol strips

3. Principle

   Results of finger blood samples from patients measured by the healthcare professional, used the BeneCheck Multi-Monitoring System and cholesterol strips while they had only the instructions and the training materials routinely provided with the BeneCheck Multi-Monitoring System. Within 5 min, a venous blood sample was collected from the same user and determined by Beckman coulter as reference. Plot the X-Y distribution of test results, and evaluation the regression and correlation.

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4. Experimental methods and procedure

4.1 Experimental chairperson: Dr. Wang from Wan Fan Hospital, Taipei Medical University.

4.2 Evaluation site: Wan Fan Hospital, Taipei Medical University.

4.3 Evaluation subjects:

Total more than 100 subjects and the selection was following JIRB request.

4.4 Age: older than 20 years old is essential.

4.4.1 Sex: No special limitation, but number of male and female had better equal

4.4.2 Limit of subjects: Hematocrit "X" of subjects is satisfied with $55\% \geq X \geq 35\%$

4.5 From the two lots cholesterol strip, we random pick up 20 vials for each lot and one vial includes 25 strips. Users pick one strip from one vial for each lot to the test.

4.6 Subjects performed to test their cholesterol with fingertip blood by the instructions of BeneCheck Multi-Monitoring System and cholesterol strips.

4.7 Immediately after the user's self-test, the investigation site's trained healthcare professional measure the user's blood with the same cholesterol monitoring system. EasyTouch and Accutrend GCT cholesterol meters were also used to measure user's finger blood by the healthcare professional.

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4.8   Beckman coulter UniCelDxC 800

Within 5 mins, venous blood samples of the user were collected by the healthcare professional, and measure the cholesterol concentration in plasma by the bio-analyzer (Beckman Coulter UniCelDxC 800) as the trueness reference value.

4.9   Repeat the procedure 6 to 8 to test by the different subjects. Change the vial after testing 5 subjects.

5.   Calculate and Statistics

5.1 Calculate the test numbers of bias% are within$\pm$15% and $\pm$ 20%. Besides, we compare the BeneCheck Multi-Monitoring System performance with EasyTouch and Accutrend GCT which are well-known commercial cholesterol monitoring systems. The tests results of plasma detected by Beckman coulter UniCeIDxC 800 will be the reference.

$$Bias\% = (Test\ result\text{-}Reference\ result) + Reference\ result\ x\ 100\%.$$

Acceptable Criteria:

The number of percentage for the bias% within should be higher than or equal to 90%.

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Results

Experimental date : 2014/08/11 – 2014/08/15.

Cholesterolstrip : 4662, 4592

Test sample: Fingertip blood and venous blood of subjects. Some extreme samples are madeup manually.

Test results:

(1)   Test results of BeneCheck Multi-Monitoring System

User number	HCT(%)	Beckman Coulter (Wanfang Hospital)	4662	4592	AVG	CV	Bias(%)
s-201	36.3%	210	235	252	243.5	4.9%	16.0%
s-202	44.0%	185.3	159	153	156	2.7%	-15.8%
s-203	35.1%	211.1		233	233		10.4%
s-204	43.5%	174.7	179	148	163.5	13.40/0	-6.4%
s-205	46.0%	140	132	129	130.5	1.6%	-6.8%
s-206	37.4%	177.7	208	168	188	15.0%	5.8%
s-207	37.0%	173.4	205	207	206	0.7%	18.8%
s-208	38.1%	201.5	200	185	192.5	5.5%	-4.5%
s-210	46.7%	144.5	149	141	145	3.9	0.3%
s-211	36.5%	160.8	173	190	181.5	6.6%	12.9%
s-212	40.2%	178	165	168	166.5	1.3%	-6.5%
s-213	49.5%	214.1	217	203	210	4.7%	-1.9%
s-215	44.2%	185.2	179	167	173	4.9%	-6.6%
s-217	35.8%	128.3	153	150	151.5	1.4%	18.1%
s-218	43.0%	148.9	150	154	152	1.9%	2.1%
s-219	42.7%	155.8	162	157	159.5	2.2%	2.4%
s-220	44.3%	113.3	134	127	130.5	3.8%	15.2%
s-221	38.40/0	169.7	167	158	162.5	3.9%	-4.2%
s-222	44.0%	168.6	165	136	150.5	13.6%	-10.7%
s-223	35.1%	143.6	170	171	170.5	0.4%	18.7%
s-224	38.5%	271.2	300	268	284	8.0%	4.7%
s-225	40.8%	214.3	227	174	200.5	18.7%	-6.4%
S-226	42%	236	225	219	222	1.9%	-5.9%

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S-227	48.0%	220.3	154	191	172.5	15.2%	-21.7%
S-228	36,4%	142.3	167	158	162.5	3.9%	14.2%
S-229	42.6%	188.8	164	169	166,5	2.1%	-11.8%
S-230	42.0%	201.9	173	160	166.5	5.5%	-17.5%
S-231	39.0%	242.9	282	243	262.5	10.5%	8.1%
S-233	40,4%	213.7%	202	174	188	10.5%	-12.0%
S-234	43.5%	239.2	252	198	225	17.0%	-5.9%
S-235	38.8%	205.1	229	187	208	14.3%	1.4%
S-236	44.4%	254.8	198	212	205	4.8%	-19.5%
S-237	36.1%	178.9	195	196	195.5	0.4%	9.3%
S-238	41.5%	202.9	231	183	207	16.4%	2.0%
S-241	36.0%	150.9	176	179	177.5	1.2%	17.6%
S-242	40.4%	166.6	152	153	152.5	0.5%	-8.5%
S-243	39.1%	206.3	160	195	177.5	13.9 %	-14.0%
S-244	30.5%	245.1	201	214	207.5	4.4 %	-15.3%
S-245	40.1%	227.9	179	183	181	1.6 %	-20.6%
S-246	36.8%	152.2	135	164	149.5	13.7 %	-1.8%
S-247	38.5%	153.9	153	165	159	5.3%	3.3%
S-248	36.6%	168.2	186	197	191.5	4.1%	13.9%
S-249	43.3%	174.5	134	157	145.5	11.2%	-16.6%
S-250	38.3%	249.2	237	206	221.5	9.9%	-11.1%
S-251	39.1%	216.2	215	183	199	11,4%	-8.0%
S-252	36.6%	172.3	203	185	194	6.6%	12.6%
S-253	42.3%	177	141	144	142.5	1.5%	-19.9%
S-254	38.8%	187.5	191	180	185.5	4.2%	-1.1%
S-255	37.9%	131.5	148	159	153.5	5.1%	16.7%
S-256	38.2%	206.9	181	178	179.5	1.2%	-13.2%
S-258	38.0%	206.6	202	223	212.5	7.0%	2.9%
S-259	36.1%	210.9	249	201	225	15.1%	6.7%
S-260	42.1%	184.5	175	215	195	14.5%	5.7%
S-261	36.6%	209.8	229	211	220	5.8%	4.9%
S-262	48.6%	209.4	236	279	257.5	11.8%	-11.3%
S-263	44.9%	106.6	124	127	125.5	1.7%	17.7%
S-264	46.2%	222	187	174	180.5	5.1%	-18.7%
S-266	36.2%	157.5	183	192	187.5	3.4%	19.0%
S-267	38.9%	177.8	200	183	191.5	6.3%	7.7%

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S-269	40.8%	199.6	234	153	193.5	29.60/0	-3.1%
S-270	37,4%	173	139	147	143	4.0%	-17.3%
S-271	41.9%	176.5	157	164	160.5	3.1%	-9.1%
S-272	40.3%	194.4	151	150	150.5	0.5%	-22.6%
S-273	43.8%	151	146	130	138	8.2%	-8.6%
S-274	39.6%	206	193	200	196.5	2.5%	-4.6%
S-275	37.8%	180.2	211	215	213	1.3%	18.2%
S-276	42.0%	174	166	143	154.5	10.5%	-11.2%
S-277	40,5%	219.5	173	208	190.5	13.0%	-13.2%
S-279	39.6%	217.8	201	173	187	10.6%	-14.1%
S-280	41.8%	184.4	164	150	157	6.3%	-14.9%
S-281	47.6%	232.4	187	171	179	6.3%	-23.0%
S-282	38.8%	143.7	159	112	135.5	24.5%	-5.7%
S-283	42.3%	163.6	178	138	158	17.9%	-3.4%
S-285	38.3%	222.1	272	225	248.5	13.4%	11.9%
S-287	45.3%	169	142	138	140	2.0%	-17.2%
S-288	37.8%	225.4	183	267	225	26,4%	-0.2%
S-289	41,4%	165.3	146	154	150%	3.8%	-9.3%
S-290	40.5%	197.9	155	203	179	19.00/0	-9.6%
S-291	38.6%	147.2	177	169	173	3.3%	17.5%
S-292	42.3%	201	173	208	190.5	13.0%	
S-293	40.6%	207	176	186	181	3.9%	-12.6%
S-294	37.3%	130.9	155	149	152	2.8%	16.1%
S-297	46.4%	243.8	156	198	177	16.8%	-27.4%
S-298	38.3%	185	157	196	176.5	15.6%	-4.6%
S-299	39,5%	185.4	160	210	185	19.1%	-0.2%
S-300	46.6%	226.5	149	182	165.5	14.1%	-26.9%
S-301	37.2%	202.8	179	195	187	6.1%	-7.8%
S-302	38.8%	140.4	136	147	141.5	5.5%	0.8%
S-303	44.5%	186.6	147	152	149.5	2.4%	-19.9%
S-304	44.0%	189.9	141	155	148	6.7%	-22.1%
S-305	39.2%	178.4	156	171	163.5	6.5%	-8.4%
S-306	37.1%	205	165	168	166.5	1.3%	-18.80/0
S-307	44.6%	161.5	145	148%	146.5	1.4%	-9.3%
S-308	42.5%	142.1	150	143	146.5	3.4%	3.1%

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(2)　　　　Test results of EasyTouch &Accutrend GCT

User number	HCT(%)	Beckman Coulter (Wanfang Hospital)	CHOL accu	CHOL easy
S-201	36.3%	210	201	
S-202	44.0%	185.3	170	231
S-203	35.1%	211.1	204	240
S-204	43.5%	174.7	173	182
S-205	46.0%	140		219
S-206	37,4%	177.7	180	202
S-207	37.0%	173.4	179	140
S-208	38.1%	201.5	161	147
S-210	46.7%	144.5	152	212
S-211	36.5%	160.8	162	190
S-212	40.2%	178	174	190
S-213	49.5%	214.1	202	217
S-215	44.2%	185.2	194	190
S-217	35.8%	128.3		182
S-218	43.0%	148.9		177
S-219	42.7%	155.8	151	212
S-220	44.3%	113.3	150	177
S-221	38,4%	169.7	178	197
S-222	44.0%	168.6	154	231
S-223	35.1%	143.6		220
S-224	38.5%	271.2	294	270
S-225	40.8%	214.3	213	251
S-226	42.0%	236	234	245
S-227	48.0%	220.3	207	243
S-228	36,4%	142.3	178	192
S-229	42.6%	188.8	189	231
S-230	42.0%	201.9	200	197
S-231	39.0%	242.9	242	251
S-233	40,4%	213.7	206	212
S-234	43.5%	239.2	228	245
S-235	38.3%	205.1	204	236

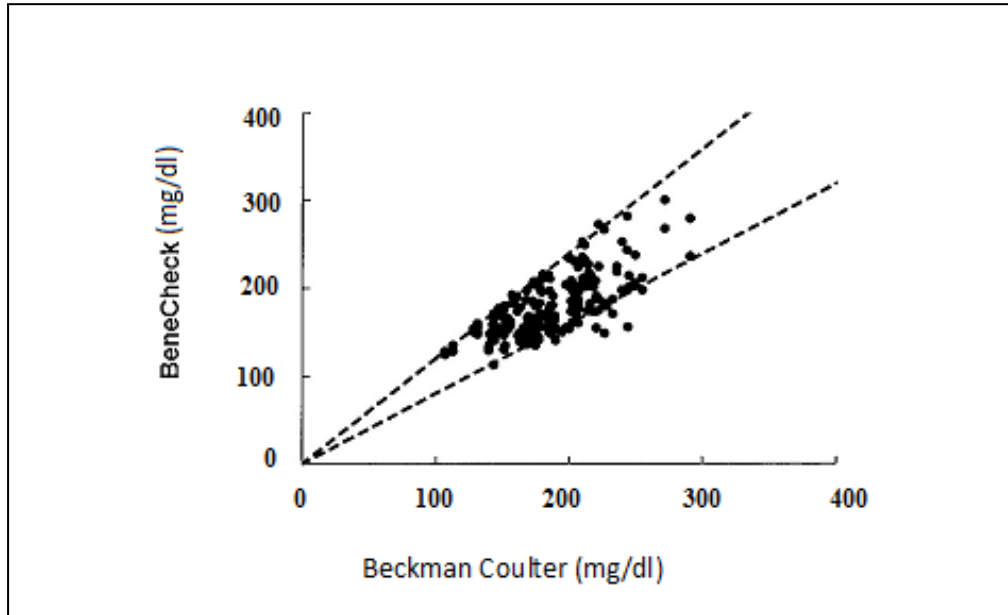| Test Subject	Clinical evaluation report of BeneCheck Multi-Monitoring System cholesterol strips		Page 9 of 14
S-236	44,4%	254.8	247	212
S-237	36.1%	178.9	178	213
S-238	41.5%	202.9	200	200
S-241	36.0%	150.9	162	182
S-242	40,4%	166.6	152	180
S-243	39.1%	206.3	204	203
S-244	40.5%	245.1	231	240
S-245	40.1%	227.9	240	245
S-246	36.8%	152.2	157	172
S-247	38.5%	153.9		190
S-248	36.6%	168.2	183	203
S-249	43.3%	174.5	166	202
S-250	38.3%	249.2	263	220
S-251	39.1%	216.2	214	212
S-252	36.6%	172.3	173	190
S-253	42.3%	177	180	205
S-254	38.3%	187.5	187	239
S-255	37,9%	131.5	140	184
S-256	38.2%	206.9	213	240
S-257	38.0%	206.6	199	256
S-259	36.1%	210.9	219	245
S-260	42.1%	184.5	173	219
S-261	36.6%	209.8	210	213
S-262	48.6%	290.4		231
S-263	44.9%	106.6	140	182
S-264	46.2%	222	213	239
S-266	36.2%	157.5		190
S-267	38.9%	177.8	188	202
S-269	40.8%	199.6	197	202
S-270	37,4%	173	173	197
S-271	41.9%	176.5		220
S-272	40.3%	194.4	191	186
S-273	43.8%	151		219
S-274	39.6%	206	207	217
S-275	37.8%	180.2	202	215
S-276	42.0%	174	185	190

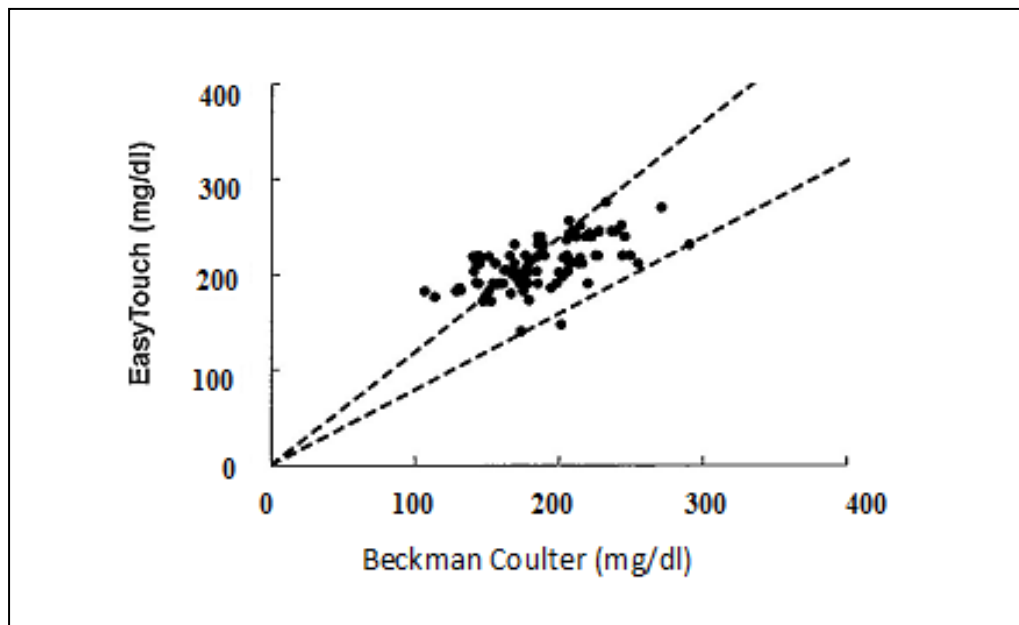| Test Subject	Clinical evaluation report of BeneCheck Multi-Monitoring System cholesterol strips			Page 10 of 14
S-277	40.5%	219.5	223	190
S-279	39.6%	217.8	232	240
S-280	41.8%	184.4	189	203
S-281	47.6%	232.4	219	276
S-282	38.8%	143.7		190
S283	42.3%	163.6	166	205
S-285	38.3%	222.1	205	240
S-287	45.3%	169	159	212
S-288	37.8%	225.4	224	220
S-289	41,4%	165.3	158	220
S-290	40.5%	197.9	200	190
S-291	38.6%	147.2	151	172
S-292	42.3%	201	200	
S-293	40.6%	207	208	212
S-294	37.3%	130.9		186
S-297	46.4%	243.8	256	220
S-298	38.3%	185	195	240
S-299	39.5%	185.4	188	220
S-300	46.6%	226.5	224	220
S-301	37.2%	202.8	194	217
S-302	38,8%	140.4		203
S-303	44.5%	186.6	188	231
S-304	44.0%	189.9	195	220
S-305	39.2%	178.4	192	173
S-306	37.1%	205	204	220
S-307	44.6%	161.5	158	205
S-308	42.5%	142.1		212

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(3)   Accuracy performance

Accuracy performance of BeneCheck two lots cholesterol strips which the Beckman Coulter result is as the reference.

Accuracy performance of EasyTouch cholesterol strips which the Beckman Coulter results is as the reference.
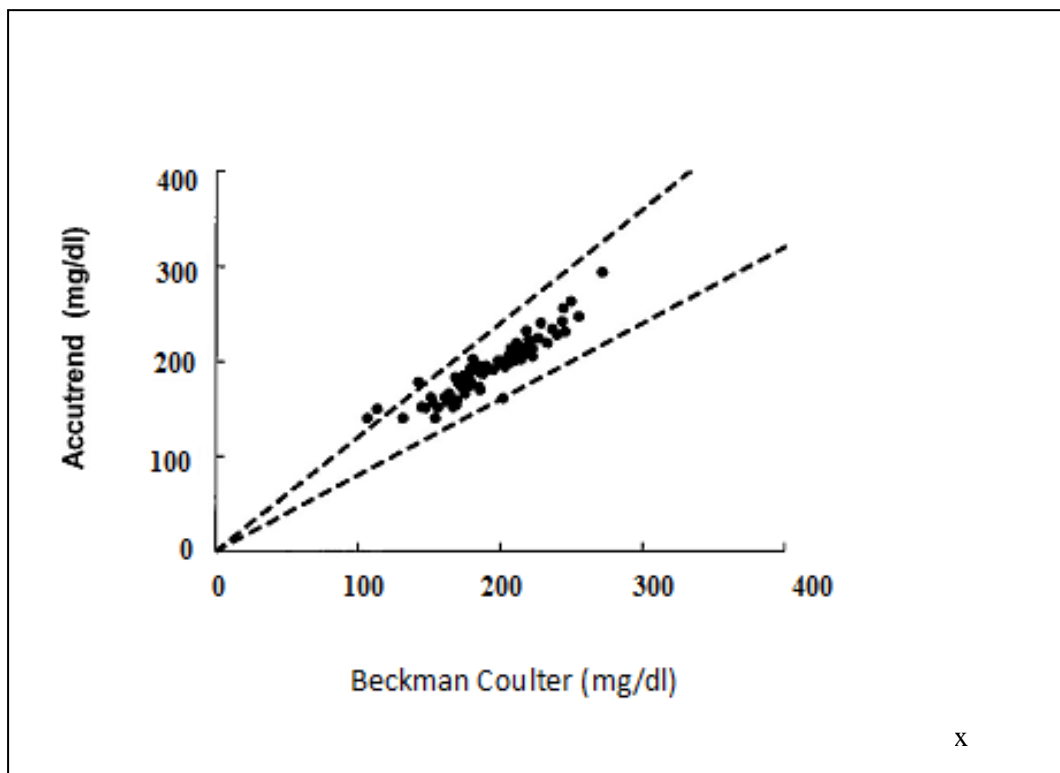
Accuracy performance of Accutrend GCT cholesterol strips which the Beckman Coulter result is as the reference.

Table 1: Linear comparison by other commercial product

	BeneCheck	**EasyTouch**	**Accutrend**
slope	0.68	0.43	0.88
R square	0.48	0.36	0.86

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5.2 Accuracy performance comparison of BeneCheck, EasyTouch and Accutrend GCT cholesterol monitoring systems.

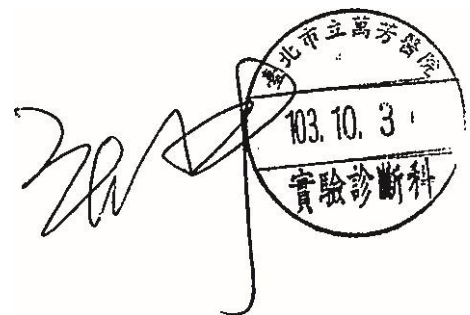Table 2 : Accuracy comparison by the reference of Beckman coulter

Beckman coulter as the reference		
Bias range	**± 20%**	**±15%**
BeneCheck	177/201	121/201
	88.1%	60.2%
EasyTouch	59/92	41/92
	64.10/0	44.60/0
Accutrend	70/79	70/79
	88.6%	88.6%

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6.   Conclusion

The statistical results showed that 88.1% of fingertip bloods fall within ± 20% bias%. At the same time, we evaluated the correlation of fingertip bloods and venous blood using analyzer. For BeneCheck Multi-Monitoring System, the slope is 0.68 and the correlation (R^2) is 0.48. For EasyTouch fingertip blood tests, the results show 64% of the test results are fall within ± 20% of the bias%, slope is 0.43 and the correlation (R^2) of 0.36. For Accutrend fingertip blood test has88.6% of the test results fall within ± 20% bias%, and slope of 0.88 and correlation ($R^{2)}$ of 0.86. Although the acceptable criteria were not satisfied, the accuracy of BeneCheck Multi-Monitoring System was very close to the accuracy of Accutrend in the evaluation. According to the results, the clinical performance evaluation provides practical reference meanings for BeneCheck Cholesterol strips.